NON-INTERVENTIONAL (NI) STUDY REPORT

PASS information

Title	A Cross-Sectional Study to Evaluate the Effectiveness of XALKORI Patient Information Brochure Among Non-Small Cell Lung Cancer (NSCLC) Patients Receiving XALKORI Treatment in Europe
Protocol number	A8081050
Version identifier of the final study report	1.0
Date of last version of the final study report	07 March 2017
EU Post Authorisation Study (PAS) register number	ENCEPP/SDPP/7393
Active substance	L01XE16/crizotinib
Medicinal product	XALKORI®
Product reference	EU/1/12/793/001-004
Procedure number	EMEA/H/C/002489
Marketing Authorisation Holder (MAH)	Pfizer Limited
Joint PASS	No

Research question and objectives	The objective of this study is to evaluate the effectiveness of XALKORI Patient Information Brochure implemented in Europe.
Country(-ies) of study	Austria, Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Sweden, and the United Kingdom
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Marketing Authorisation Holder(s)

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1. ABSTRACT (STAND-ALONE DOCUMENT)

2. LIST OF ABBREVIATIONS

Abbreviation	Definition
AE	Adverse event
ALK	Anaplastic lymphoma kinase
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
CAS	Completer analysis set
CHMP	Committee for Medicinal Products for Human Use
CI	Confidence interval
ECG	Electrocardiogram
EMA	European Medicines Agency
EML4	Echinoderm microtubule-associated protein-like 4
ESMO	European Society for Medical Oncology
FAS	Full analysis set
EU	European Union
FDA	Food and Drug Administration
IEC	Independent Ethics Committee
ILD	Interstitial lung disease
IMS	Intercontinental Marketing Services
NIS	Non-interventional study
NSCLC	Non-small cell lung cancer
PASS	Post-Authorisation Safety Study
PIB	Patient information brochure
PIL	Patient Information Leaflet
SAP	Statistical analysis plan
SmPC	Summary of Product Characteristics
SOP	Standard operating procedures
TMG	Therapeutic management guide
UK	United Kingdom
US	United States

3. INVESTIGATORS

The names, affiliations, and contact information of the investigators at each study site are listed in Appendix 3.

Principal Investigator(s) of the Protocol

Name, degree(s)	Title	Affiliation
Kui Huang, PhD, MPH	Senior Director, Epidemiology	Pfizer Inc.

4. OTHER RESPONSIBLE PARTIES

Responsible Party Name and Affiliation	Role in the study
Terri Madison, PhD, MPH Mapi 2343 Alexandria Drive, Suite 100 Lexington, KY 40504 USA Philippe Huot-Marchand, MSc Mapi 27 rue de la Villette 69003 Lyon France	Data analysis and study report

5. MILESTONES

Milestone	Planned date	Actual date	Comments
Date of Independent Ethics Committee (IEC) approval of protocol The IEC approval dates for the protocol and any amendments are provided in Appendix 3.	15 Feb 2015*	1st IEC approval: 25 Mar 2015 Last IEC approval: 23 May 2016	IEC approval was required in Belgium, Germany, Ireland, Italy, Sweden, and the UK
Start of data collection**	30 September 2014	30 September 2014	
End of data collection	30 September 2016	30 September 2016	
Registration in the EU PAS register	02 September 2014	02 September 2014	
Final report of study results	30 March 2017	07 March 2017	

*First IEC submission in Belgium on 14 Jan 2015; usual timeline for approval 28 days depending on when local sessions are scheduled.
**Data collection started in Denmark, which did not require IEC approval.

6. RATIONALE AND BACKGROUND

Lung cancer is the leading cause of cancer-related mortality worldwide, and it is estimated that more patients will die of lung cancer than of breast, colon, and prostate cancer combined. In 2012, the number of new lung cancer cases worldwide was estimated at 1.8 million, or 12.9% of all new cancers, and the number of lung cancer deaths at 1.59 million, or 19.4% of the total cancer deaths (Globocan, 2012).[1] In Europe, estimates for the year 2012 were 449,000 new cases of lung cancer and 388,000 deaths (Globocan, 2012).[1] The majority of lung cancers (85%) is non-small cell lung cancer (NSCLC) (Jemal et al, 2011)[2] and is mainly inoperable locally advanced (Stage IIIB) or metastatic (Stage IV) disease for which no curative treatment is available.

With the evolving understanding of the molecular basis of the disease, agents that target specific pathways, particularly in genetically defined subsets of patients, have become an increasing focus of cancer drug development. One of the newer molecular targets identified in NSCLC is the echinoderm microtubule-associated protein-like 4 (EML4)-anaplastic lymphoma kinase (ALK) fusion oncogene. ALK-positive NSCLC constitutes a molecularly defined subgroup with an estimated prevalence of 2.7% of NSCLC (Varella-Garcia, et al, 2010).[3]

XALKORI is a selective small-molecule inhibitor of the ALK receptor tyrosine kinase and its oncogenic variants (i.e., ALK fusion events and selected ALK mutations). XALKORI received marketing approval in the United States (US) in August 2011 for the treatment of patients with metastatic NSCLC whose tumours are ALK-positive as detected by a Food and Drug Administration (FDA)-approved test. Subsequently, XALKORI received approval in the European Union (EU) for the treatment of adults with previously treated and previously untreated ALK-positive advanced NSCLC. Currently, XALKORI has received marketing authorisation approvals globally for the treatment of ALK-positive advanced NSCLC in over 90 countries, including Australia, Canada, China, Japan, South Korea, Switzerland, and Taiwan. XALKORI was also approved in the US and EU for the treatment of patients with advanced NSCLC whose tumours are ROS1 positive in March and August 2016, respectively.

A number of safety risks have been associated with XALKORI including hepatotoxicity, interstitial lung disease (ILD)/pneumonitis, QTc prolongation, bradycardia, and vision disorders. Each of these risks is listed as an adverse reaction in the XALKORI label or Summary of Product Characteristics (SmPC). Pfizer has developed educational materials in Europe as part of risk minimisation measures requested by the Committee for Medicinal Products for Human Use (CHMP), which include a patient information brochure (PIB) and a therapeutic management guide (TMG) to further inform patients with ALK-positive NSCLC receiving XALKORI treatment and physicians prescribing XALKORI, respectively, about known risks associated with XALKORI.

The PIB includes information on adverse reactions with a focus on vision disorders and QTc prolongation. The PIB also comprises the information on hepatotoxicity, ILD/pneumonitis, and bradycardia. In addition, a patient identification (ID) card is included in the PIB, which instructs patients to fill out the card with their name, their oncologist's name, and start date of XALKORI treatment and to present the card to their other healthcare providers. This study was designed to evaluate the effectiveness of the XALKORI PIB in the EU. This non-interventional study (NIS) was designated as a Post-Authorisation Safety Study (PASS) and was a commitment to the European Medicines Agency (EMA). Pfizer submitted the final draft study protocol to EMA prior to the start of the study and the protocol was endorsed by the EMA.

7. RESEARCH QUESTION AND OBJECTIVES

The overall objective of this study was to evaluate the effectiveness of the XALKORI PIB implemented to mitigate the risks of hepatotoxicity, ILD/pneumonitis, QTc prolongation, bradycardia, and vision disorders in 10 countries in the EU: Austria, Belgium, Denmark, France, Germany, Ireland, Italy, the Netherlands, Sweden, and the United Kingdom (UK).

Specifically, the objectives of the study were to:

- assess the patients' awareness of the PIB and the patient ID card included in the PIB by estimating the proportion of patients who acknowledged receiving the PIB,
- evaluate the patients' utilisation of the PIB by estimating the proportion of patients who acknowledged reading the PIB and using the patient ID card, and
- assess the patients' knowledge/comprehension of the risks of hepatotoxicity, ILD/pneumonitis, QTc prolongation, bradycardia, and vision disorders by estimating the proportion of patients with correct responses to risk knowledge/comprehension questions.

8. AMENDMENTS AND UPDATES

A summary of amendments to the protocol is provided in In-text Table 1. The most recent amended protocol is provided in Appendix 2. In order to mitigate the low response rate, the protocol was substantially amended in March 2015 to add 4 additional countries (Austria, Ireland, Sweden, and the UK) to expand the list of physicians able to recruit patients receiving XALKORI, and to extend the survey to remain open for an additional 12 months to complete the additional recruitment. Pfizer submitted the substantial protocol amendment version 1.2 to the EMA and the amended protocol was endorsed by the EMA.

In-text Table 1. Amendments to the Protocol

Amendment number	Date	Substantial or administrative amendment	Protocol section(s) changed	Summary of amendment	Reason
1.1	4 December 2014	Administrative	1. PASS information page 2. Section 10.1 3. Appendix 1	1. Added EU PAS registration number 2. Changed the wording on the second bullet point 3. Replaced the draft patient survey questionnaire with the final patient survey questionnaire	1. The study is now registered at EU PAS register 2. The new wording reflects on informed consent practice in participating European countries for a patient survey when an informed consent is needed 3. The draft survey questionnaire was pretested and the final survey questionnaire incorporated comments from patients who did the pretesting
1.2	30 March 2015	Substantial amendment	1. PASS information page 2-3. List of abbreviation, Abstraction, Milestone, and Sections 8 and 9.	1. Added 4 more countries to the survey 2. Extended the recruitment period from 1 year (i.e., September 2014-September 2015) to 2 years (i.e., September 2014-September 2016) 3. Changed the date for the final study report from March 2016 to March 2017	1. The survey was initiated in September 2014. The response rate has been low. Adding more countries will add a pool of patients for the survey. 2. The extension of recruitment is necessary to achieve the target number of patients completing the survey because of the low response rate 3. It is necessary to change the date of the final study report because the recruitment period is extended from 1 year to 2 years

9. RESEARCH METHODS

9.1. Study design

This was a cross-sectional study of patients that collected information on the distribution of the XALKORI PIB, the level of awareness of key risk messages, and the level of knowledge of key risk messages in the XALKORI PIB. The study was conducted in patients with ALK-positive NSCLC who received XALKORI treatment within 90 days prior to taking the survey from September 2014 to September 2016 in 10 countries including Belgium, Denmark, France, Germany, Italy, the Netherlands, Sweden, Austria, Ireland, and the UK.

9.2. Setting

A non-probability sample (i.e., convenience sample) of patients with ALK-positive NSCLC who received XALKORI treatment in 10 participating countries including Belgium, Denmark, France, Germany, Italy, the Netherlands, Sweden, Austria, Ireland, and the UK was recruited through their treating medical oncologists or pulmonologists from September 2014 through September 2016. A mailing list of these potential treating medical oncologists

or pulmonologists in the 10 participating countries was obtained from the Intercontinental Marketing Services (IMS) commercial database. Thus, patients with ALK-positive NSCLC who received XALKORI treatment by physicians on this list in the participating countries were considered the potential survey population for this patient survey. Treating medical oncologists or pulmonologists are not required to participate in the XALKORI physician survey in order to recruit patients for the patient survey.

9.3. Subjects

9.3.1. Eligibility criteria

To determine patients' eligibility to participate in the study, screening questions were included in the introduction of the survey.

9.3.1.1. Inclusion criteria

To be eligible to participate in the study, patients must have met all of the following inclusion criteria:

- patients must be treated with XALKORI as per SmPC at least 1 dose within 90 days prior to taking the survey, and
- evidence of a personally signed and dated informed consent document indicating that the patient has been informed of all pertinent aspects of the study if the informed consent is required by local laws and regulations.

9.3.1.2. Exclusion criteria

Patients meeting any of the following criteria were ineligible to participate in the study:

- participated in the pre-testing of the survey for the study, or
- had immediate family members who have worked for Pfizer, Mapi (the study vendor), or the EMA within the past 10 years.

9.3.2. Potential Participant Selection

Potential participants of the survey were identified by their treating physicians. Lists of actual XALKORI-treated patients were not available for study recruitment and the actual distribution of XALKORI use by country was unknown. In all countries except Belgium and Italy, physicians who identified potential patient survey participants had either participated in the physician survey pre-testing or completed the physician survey, and indicated their willingness to identify patients for the patient survey. In Belgium and Italy, participating institutions were able to participate in both the patient and physician surveys, but were not required to participate in both surveys.

With study participation being voluntary, a representative distribution could not be guaranteed.

Patients in Belgium, Germany, and the Netherlands were compensated for their time to complete the survey via a gift card. Patients who completed the survey in all other participating countries were not offered a gift card either due to local restrictions and/or the recommendation of the local Pfizer Country Office.

9.4. Variables

Variables evaluated in the study consisted of 5 key risk messages included in the XALKORI PIB.

1. **Visual effects (i.e., Vision disorders):** You may experience some visual effects. In most cases, these arise within 1 week after starting treatment and could include: flashes of light, blurred vision, and double vision. Please be especially careful when driving or operating machinery. You may need to stop these activities if you feel that the changes to your vision prevent you from doing these activities safely. Sometimes these changes get better over time. However, if you experience changes that persist, or that seem to get worse over time, you should inform your doctor, who may refer you to an eye doctor for an examination.

2. **Light-headedness, fainting, chest discomfort, irregular heartbeat (i.e., QTc prolongation)**: Tell your doctor right away if you experience these symptoms which could be signs of changes in the electrical activity (seen on electrocardiogram) or rhythm of the heart. If you have a pre-existing heart condition, your healthcare professional will closely monitor your heart function and may adjust your XALKORI dosage. Your doctor may perform electrocardiograms to check that there are no problems with your heart during treatment with XALKORI.

3. **Liver damage (i.e., hepatotoxicity):** Regular blood tests are conducted during therapy with XALKORI. This allows monitoring the function of various organs including the liver. Please inform your doctor immediately: if you feel more tired than usual, your skin and whites of your eyes turn yellow, your urine turns dark or brown (tea colour), you have nausea, vomiting, or decreased appetite, you have pain on the right side of your stomach, you have itching, or if you bruise more easily than usual. These may be signs that your liver is affected by the treatment, and your doctor may perform blood tests to check your liver function. If the results are abnormal, your doctor may decide to reduce the dose of XALKORI or stop your treatment. If you experience any of the above symptoms, contact your doctor immediately, and do not wait for your next clinic visit.

4. **Breathing problems (i.e., ILD/pneumonitis):** A potential side-effect is a non-infectious inflammation of the lungs. After starting your XALKORI treatment, if you experience any new complaints such as difficulties with breathing, cough, fever, or if any existing conditions get worse, inform your doctor immediately.

5. **Reduced heart rate (i.e., bradycardia):** XALKORI may cause reduced heart rate. Your doctor will monitor your heart function and may adjust your XALKORI dosage.

In addition, the study also collected information on whether the patients were aware of, received, and read the XALKORI PIB. Brief demographic characteristics of respondents were also collected.

9.5. Data sources and measurement

9.5.1. Cognitive pre-testing of the survey questionnaire

The survey questionnaire underwent cognitive pre-testing with 8 XALKORI-treated patients who met the study's eligibility criteria, specifically, 1 XALKORI-treated patient each from Denmark, France, Germany, Italy, the Netherlands, and Sweden and 2 XALKORI-treated patients from Belgium (1 for Belgium in French, the other in Flemish). The objective of the pre-test was to identify any survey questions that required clarification or revision based on areas of confusion or miscomprehension revealed by participants in the cognitive pre-test interviews. Pre-testing was planned to be conducted with 1 XALKORI-treated patient per language per country; however, it was decided to not pre-test in Austria given that the instrument had already been pre-tested in German and there were limited differences in the questionnaire between Germany and Austria. Since the English version of the questionnaire had already been endorsed by the EMA, it was also decided to not pre-test in Ireland or the UK. Nevertheless, the survey questionnaire was reviewed by Pfizer Austria, Pfizer Ireland, and Pfizer UK to ensure that questions and response choices were aligned with the local XALKORI materials and norms, as applicable.

Pre-testing was completed through 1-on-1 interviews conducted by personnel experienced in the conduct of cognitive pre-testing and linguistic validation of survey questionnaires. XALKORI-treated patients for the pre-test were recruited by physicians who identified a XALKORI-treated patient from their practices.

During the conduct of the pre-test, the survey questionnaire was presented item by item, and feedback was obtained for each question using a pre-developed interviewer guide. The interviewer also recorded information regarding any questions received by patients or other observations indicating difficulty with any particular question or wording.

The cognitive pre-test resulted in minor revisions to almost all of the country-specific versions of the patient questionnaire. For all countries, minor changes to adjust the initial translations to accommodate local standards or ways of saying things were identified, (e.g., in some countries, "true/false" was more commonly expressed as "yes/no", educational levels for the patient survey were adapted to be consistent with local standards, etc.). Other changes identified from pre-testing were:

- Throughout the survey, the generic name for XALKORI (i.e., crizotinib) was added in parentheses as several patients did not recognize the brand name.

- For France, the translation for instructions when asking about side effects associated with XALKORI (Question 1) was revised to clarify that the objective was to ask about information learned from the Patient Information Brochure rather than to learn of any side effects actually experienced by the patient.

9.5.2. Screening and survey administration

Patient survey data were collected through self-administered internet surveys or paper surveys, depending on patient preference, and in local languages.

The survey questions consisted primarily of yes/no and true/false questions and it was expected that completion of the entire survey would take approximately 15 minutes. The survey began with screening questions to determine patients' eligibility. Depending on the answers to the screening questions, survey participation could either be terminated or continued. If eligible, patients were able to continue to the main survey questions, where the majority of questions evaluated the key risk messages for XALKORI. The detailed questions for the survey are provided in Appendix 5.

Patient survey kits were sent out in batches to physicians who expressed their willingness to recruit patients for the patient survey, once physicians had secured any required local approvals such as ethics committees. The patient survey kit included:

- a survey invitation letter with information about the study, a unique code, and instructions for accessing the survey on-line,

- for all countries except France, an informed consent document to be completed in discussion between the patient and their treating physician; in France, a study information sheet was provided in place of the informed consent as per local regulations,

- a blank paper survey (same unique code) and postage paid, pre-addressed envelope to return the paper survey, should the patient choose to complete the survey on paper rather than on-line, and

- for Belgium, Germany, and the Netherlands, an inactivated gift card (same unique code) as an appreciation for patients' valuable time and input by completing the survey.

The unique code was used by Mapi to activate gift cards once the corresponding completed surveys were received, as well as to track surveys received by physicians so that reminders based on completed surveys could be sent to treating physicians/sites whose patients had not completed the patient survey.

The study period was from 30 September 2014 to 30 September 2016 allowing 24 months for data collection. Metrics on survey completion were tracked to monitor progress (e.g., number of completed surveys) and to identify physicians/sites whose patients had no or low completed patient surveys.

9.6. Bias

A primary limitation of survey studies in general is selection bias due to use of a convenience sample and/or low response rates. Given that it was not feasible to have a random sample of patients to participate in the study, to minimise selection bias for this study, all efforts were made to identify physicians from all participating countries to recruit patients, targeting physicians who self-identified as having treated at least 1 patient with ALK-positive NSCLC with XALKORI within the last 12 months.

Another source of potential bias is that the study relied on self-reporting. It is possible that patients may inaccurately report the information most likely due to recall bias.

To minimise information bias, response sets for all multiple choice questions were randomised for the on-line survey. Patients were also instructed to complete the survey in 1 sitting to minimise the likelihood of looking up the correct answers, and for the on-line survey, were not able to revise their answers after advancing to each subsequent question. Additionally, patients' treating physicians were intentionally not contacted to ask patients who completed a survey to clarify or revise their survey responses.

9.7. Study Size

The initial sample size was 50 patients completing the survey. The sample was determined based on both practical and statistical considerations taking into account the rarity of ALK-positive NSCLCs (2.7% of all NSCLCs) (Varella-Garcia, et al, 2010)[3] and the low response rate in cross-sectional studies (a typical response rate for a survey ranges from 2% to 10%). In-text Table 2 shows precision and 2-sided 95% confidence intervals (CIs) for various combinations of sample size and levels of understanding. For example, assuming 30 patients would complete the survey and a percentage of correct responses to survey questions among these patients is 80%, then the corresponding precision and 95% CI are 15.5% and 61.4%–92.3%. The CI for 1 proportion with exact (Clopper-Pearson) formula from PASS software (version 2008.0.5)[4] was used for the calculations. If the estimated number of completed surveys was met before the end of the study, the study planned to continue to recruit patients until the end of study.

In spite of multiple efforts to increase the number of participants (e.g., added additional countries, extended the study period), the number of completed surveys was still low. In June 2016, the EMA endorsed Pfizer's proposal to decrease the sample size from 50 to 25–40 patient completing surveys in 10 participating countries.

In-text Table 2. Precision and 95% Confidence Intervals (2-sided) for Various Combinations of Sample Sizes and Rates of Correct Responses

Sample size	Rate of correct responses (%)	Precision (%)	Estimated Confidence Interval (%)
30	50	±18.7	31.3-68.7
30	60	±18.4	40.6-77.3
30	70	±17.4	50.6-85.3
30	80	±15.5	61.4-92.3
50	50	±14.5	35.5-64.5
50	60	±14.2	45.2-73.6
50	70	±13.4	55.4-82.1
50	80	±11.9	66.3-90.0
80	50	±11.4	38.6-61.4
80	60	±11.2	48.4-70.8
80	70	±10.5	58.7-79.7
80	80	±9.3	69.6-88.1
100	50	±10.2	39.8-60.2
100	60	±10.0	49.7-69.7
100	70	±9.4	60.0-78.8
100	80	±8.3	70.8-87.3

9.8. Data transformation

Surveys were entered in Confirmit, a software platform specifically designed for the creation, delivery, analysis, and reporting of surveys. Data collected in this study were stored at secure servers, and were maintained by trained statisticians and data managers, ensuring compliance with local or national regulations.

Prior to database lock, the database underwent a final review by the project data manager, statistician, and epidemiologist. The main recommendation from this review was to remove empty surveys, where respondents had accessed the survey, but had not completed any of the survey questions. Other changes were 2 self-evident corrections, where for 2 patients who skipped the question "Do you know whether there is a card (i.e., a patient ID card) in the Patient Information Brochure for XALKORI?", a response of "Yes" was added, because these 2 patients provided an answer to the question which followed ("Have you ever used the card by telling your other doctors you are on XALKORI treatment?"). The database was locked on 25 October 2016.

Detailed methodology for data transformations, particularly complex transformations (e.g., many raw variables used to derive an analytic variable), are documented in the Statistical Analysis Plan (SAP), which is dated, filed, and maintained by the sponsor (Appendix 4).

9.9. Statistical methods

All patients who met the inclusion/exclusion criteria (see Section 9.3.1) and provided a response to at least 1 of the main questions (main survey questions 1 to 14; these questions succeed the 4 inclusion/exclusion questions [Appendix 5]) were considered in the full analysis set (FAS) population. Patients from the FAS who completed all core survey questions were considered in the completer analysis set (CAS) population. The core survey

questions were questions that enabled the assessment of effectiveness endpoints (survey questions 1A-1I, 2A-2C, 3A-3G, 4, 5, and 13 [Appendix 5]). During the finalization of the tables and drafting of the report, the core survey questions were revised to remove question 13, as this question was intentionally skipped if the answer to question 5 was not "yes".

9.9.1. Main summary measures

The main endpoints are summarised in this section. Details regarding the derivation of all items that comprised the main endpoints are provided in the SAP (Appendix 4).

9.9.1.1. Main effectiveness endpoints

The main objectives assessed were:

- the rates of awareness, receipt, and use of the XALKORI PIB and patient ID card,
- knowledge rates of the known risks (side effects) associated with XALKORI,
- knowledge rates of XALKORI precautions for use, and
- knowledge rate of reasons for calling a doctor.

Rates of awareness, receipt, and use of the XALKORI PIB and patient ID card were derived as the proportion of patients who answered "Yes" to the corresponding questions on the survey questionnaire. Knowledge rates were derived as the proportion of patients who provided correct responses to the corresponding questions regarding (1) known risks (side effects) associated with XALKORI, (2) XALKORI precautions for use, and (3) reasons for calling a doctor.

9.9.1.2. Other effectiveness endpoints

Other effectiveness endpoints were:

- Distribution of all response choices to XALKORI side effects questions,
- Distribution of all response choices to precautions for use of XALKORI questions,
- Distribution of all response choices to reasons for calling a doctor questions,
- Distribution of all response choices to questions on PIB awareness, receipt, and use,
- The number and percentage of patients with correct responses (composite endpoints) to all survey questions regarding XALKORI side effects, overall and stratified by reading of the XALKORI PIB,
- The number and percentage of patients with correct responses (composite endpoints) to all survey questions regarding precautions for use of XALKORI, overall and stratified by reading of the XALKORI PIB, and

- The number and percentage of patients with correct responses (composite endpoints) to all survey questions regarding reasons for calling a doctor questions, overall and stratified by reading of the XALKORI PIB.

9.9.2. Main statistical methods

Detailed statistical methods are described in the SAP (Appendix 4). All analyses were descriptive and were conducted using SAS® version 9.2; AdClin® version 3.1.4 was used to format tables.

Qualitative variables were described by the absolute and relative (%) frequency of each category and number of missing data. Missing data were taken into account in the percentage calculation. Two-sided 95% CI for proportions were calculated for the effectiveness endpoints using exact methods. No statistical tests were performed.

All analyses were performed overall, and by country. Analyses of the effectiveness of the XALKORI PIB and awareness and utilisation of the PIB and patient ID card were stratified by:

- Reading of the XALKORI PIB (Read / Not read or not received),
- Age group (18-64/65 or older), and
- Education level (Primary school / Secondary school / University/higher education / Prefer not to answer)

9.9.3. Missing values

Missing data were reviewed solely for the purposes of deriving the effectiveness endpoints and completer analysis population. No replacement or imputation was performed. Missing data were taken into account in the percentage calculations when missing number is reported.

9.9.4. Sensitivity analyses

None.

9.9.5. Amendments to the statistical analysis plan

Rates of use of the XALKORI PIB and patient ID card were derived as the proportion of patients who answered “Yes” to the corresponding questions on the survey questionnaire. In calculating these rates, analyses originally used the full denominators of the FAS and CAS. After review of the Draft 1 study report, it was decided to change the denominators for these questions to reflect skip patterns built into the questionnaire so that the calculation of rates used only the applicable denominator of patients for these questions. For example, if a patient answered “no” to receipt of the XALKORI PIB, the questionnaire skipped the subsequent question regarding use of the XALKORI PIB, and therefore that patient should not have been included in the denominator when calculating the rate.

9.10. Quality control

This was a survey study to evaluate the effectiveness of the XALKORI PIB by estimating the proportion of XALKORI-treated patients who responded correctly to questions regarding information included in the XALKORI PIB. Applicable aspects of Mapi's standard operating procedures (SOPs) to ensure data quality and integrity were followed, including documentation of data validation and cleaning and validation of statistical programming. Based on social science research principles for knowledge assessment surveys, in order to reduce bias from asking respondents to change their original survey responses *post hoc*, limited data validation and cleaning was performed.

9.11. Protection of human subjects

Patient information and consent

Written informed consent was obtained prior to the patient completing the survey. The nature, purpose, and duration of the study were described on the informed consent to each patient. Each patient was informed that he/she could withdraw from the study at any time and for any reason. Each patient was given sufficient time to consider the implications of the study before deciding whether to participate. In 9 of the 10 participating countries, patients who chose to participate signed an informed consent document. In France, this was not required, and instead patients received a study information sheet with essentially analogous information to what was provided in the informed consent document.

Independent Ethics Committee (IEC)

The final protocol, any amendments, and informed consent documentation were reviewed and approved by an IEC for each site/country (as applicable based on local regulations) participating in the study.

Ethical conduct of the study

The study was conducted in accordance with legal and regulatory requirements, as well as with scientific purpose, value and rigor and follows generally accepted research practices described in the EMA Guideline on Good Pharmacovigilance Practices Module VIII (Post-Authorisation Safety Studies) and Module XVI (Risk Minimisation Measures), *Guidelines for Good Pharmacoepidemiology Practices* issued by the International Society for Pharmacoepidemiology, Good Epidemiological Practice guidelines issued by the International Epidemiological Association, International Ethical Guidelines for Epidemiological Research issued by the Council for International Organisations of Medical Sciences, and EMA European Network of Centres for Pharmacoepidemiology and Pharmacovigilance Guide on Methodological Standards in Pharmacoepidemiology.

10. RESULTS

10.1. Participants

A summary of survey administration details and patient eligibility is provided in In-text Table 3 (Section 15, Table 1). A total of 341 patient survey kits were sent to 56 physicians/sites who initially agreed to recruit patients for the patient survey across the 10 participating countries. Among these 56 physicians, 15 physicians recruited a total of 40 patients who either accessed the on-line survey or submitted a paper survey and completed at least 1 question, giving a survey response rate (defined as the number of patients who responded to the survey divided by the total number of patient survey kits being sent to treating physicians) of at least 11.7% (40/341). The true response rate could be higher, as it was not known how many of the 341 patient survey kits sent to physicians were actually distributed to patients. Of these, 1 patient (2.5%) was ineligible due to self or a family member employed by Pfizer, Mapi, or the EMA within the last 10 years. The rest of the 39 patients who completed the main survey met the study eligibility requirements and were included in the FAS population (met eligibility criteria and completed at least 1 main survey question). Thirty-four patients were included in the CAS population (FAS subgroup who completed all core survey questions). The core survey questions were questions that enabled the assessment of effectiveness endpoints.

No completed patient surveys were received from Denmark, Ireland, or the UK and therefore no results from these 3 countries are presented in subsequent in-text tables.

In-text Table 3. Survey Administration, Eligibility, and Analysis Sets Overall and by Country

	Overall	Austria	Belgium	Denmark	France	Germany	Ireland	Italy	Netherlands	Sweden	United Kingdom
	N (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Number of patient survey kits sent to physicians	341	20	44	22	95	45	25	50	20	15	5
Number of surveys collected[a]	40 (11.7)	2 (10.0)	5 (11.4)	0 (0.0)	1 (1.1)	9 (20.0)	0 (0.0)	18 (36.0)	1 (5.0)	4 (26.7)	0 (0.0)
Survey modality[b]				N/A			N/A				N/A
Paper	36 (90.0)	2 (100.0)	4 (80.0)		1 (100.0)	9 (100.0)		16 (88.9)	1 (100.0)	3 (75.0)	
On-line	4 (10.0)	0 (0.0)	1 (20.0)		0 (0.0)	0 (0.0)		2 (11.1)	0 (0.0)	1 (25.0)	
Eligible[b]				N/A			N/A				N/A
Yes	39 (97.5)	2 (100.0)	5 (100.0)		1 (100.0)	9 (100.0)		17 (94.2)	1 (100.0)	4 (100.0)	
No	1 (2.5)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		1 (5.6)	0 (0.0)	0 (0.0)	
If no: reasons for exclusion											
Not agree to take part in this survey	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	0 (0.0)	
Patient not treated with at least 1 dose of XALKORI within the past 90 days	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	0 (0.0)	
Participation in the pre-testing survey	0 (0.0)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	0 (0.0)	
Self or family members employed by Pfizer, Mapi, or EMA in the past 10 years	1 (100.0)	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)		1 (100.0)	0 (0.0)	0 (0.0)	
Analysis Sets[c]				N/A			N/A				N/A
FAS (Eligible patients who have completed at least 1 main question[d])	39 (100.0)	2 (100.0)	5 (100.0)		1 (100.0)	9 (100.0)		17 (100.0)	1 (100.0)	4 (100.0)	
CAS (Eligible patients who have completed all core questions[e])	34 (87.2)	2 (100.0)	5 (100.0)		1 (100.0)	7 (77.8)		14 (82.4)	1 (100.0)	4 (100.0)	

CAS=Completer Analysis Set, EMA=European Medicines Agency, FAS=Full Analysis Set, N/A=not applicable.
[a] Denominator= no. of patient survey kits sent
[b] Denominator= surveys collected
[c] Denominator=eligible patients
[d] Main survey questions= questions 4-14
[e] Core survey questions= questions 1A-1I, 2A-2C, 3A-3G, 4, and 5

10.2. Descriptive data

In-text Table 4 provides a summary of characteristics of respondents for the FAS overall and by country. Although results are presented overall and also stratified by country, due to the small number of respondents, results by country will not be discussed. Table 2 and Table 3 in Section 15 provide the corresponding summaries of respondent characteristics for the FAS and CAS, respectively.

Most respondents were female (71.8%), were <65 years of age (76.9%), and had been treated with XALKORI within the last month (82.1%). A majority of patients were not currently participating in a XALKORI clinical trial (56.4%). One-third of respondents had completed university/higher education.

In-text Table 4. Patient Characteristics Overall and by Country – Full Analysis Set

	Overall N=39	Austria n=2	Belgium n=5	France n=1	Germany n=9	Italy n=17	Netherlands n=1	Sweden n=4
Last time treated with XALKORI (n [%])								
Within the last month	32 (82.1)	2 (100.0)	3 (60.0)	1 (100.0)	7 (77.8)	14 (82.4)	1 (100.0)	4 (100.0)
1 month ago	2 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	1 (5.9)	0 (0.0)	0 (0.0)
2 months ago	3 (7.7)	0 (0.0)	2 (40.0)	0 (0.0)	1 (11.1)	0 (0.0)	0 (0.0)	0 (0.0)
3 months ago	2 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (11.8)	0 (0.0)	0 (0.0)
I don’t know	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MD	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Current participant in a XALKORI clinical trial (n [%])								
Yes	11 (28.2)	0 (0.0)	0 (0.0)	1 (100.0)	2 (22.2)	7 (41.2)	1 (100.0)	0 (0.0)
No	22 (56.4)	2 (100.0)	3 (60.0)	0 (0.0)	6 (66.7)	7 (41.2)	0 (0.0)	4 (100.0)
I don't know	6 (15.4)	0 (0.0)	2 (40.0)	0 (0.0)	1 (11.1)	3 (17.6)	0 (0.0)	0 (0.0)
MD	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gender (n [%])								
Male	11 (28.2)	0 (0.0)	3 (60.0)	0 (0.0)	3 (33.3)	5 (29.4)	0 (0.0)	0 (0.0)
Female	28 (71.8)	2 (100.0)	2 (40.0)	1 (100.0)	6 (66.7)	12 (70.6)	1 (100.0)	4 (100.0)
Prefer not to answer	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
MD	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Age group (n [%])								
18-44	9 (23.1)	0 (0.0)	0 (0.0)	0 (0.0)	1 (11.1)	7 (41.2)	0 (0.0)	1 (25.0)
45-54	8 (20.5)	2 (100.0)	1 (20.0)	0 (0.0)	3 (33.3)	2 (11.8)	0 (0.0)	0 (0.0)
55-64	13 (33.3)	0 (0.0)	3 (60.0)	0 (0.0)	3 (33.3)	5 (29.4)	0 (0.0)	2 (50.0)
65-74	7 (17.9)	0 (0.0)	1 (20.0)	1 (100.0)	2 (22.2)	2 (11.8)	0 (0.0)	1 (25.0)
75 or older	2 (5.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	1 (100.0)	0 (0.0)
MD	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Educational level (n [%])								
Primary school	7 (17.9)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	6 (35.3)	0 (0.0)	0 (0.0)
Secondary school	11 (28.2)	0 (0.0)	4 (80.0)	0 (0.0)	2 (22.2)	5 (29.4)	0 (0.0)	0 (0.0)
University/higher education	13 (33.3)	1 (50.0)	1 (20.0)	1 (100.0)	0 (0.0)	6 (35.3)	1 (100.0)	3 (75.0)
Prefer not to answer	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (25.0)
MD	7 (17.9)	0 (0.0)	0 (0.0)	0 (0.0)	7 (77.8)	0 (0.0)	0 (0.0)	0 (0.0)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
MD=Missing data

10.3. Outcome data

Endpoints were tabulated for both the FAS and CAS populations (Section 15). Although only 34 of the 39 respondents completed all core survey questions, each individual core survey question was completed by a minimum of 37 of the 39 respondents. Therefore, results are discussed for the FAS population only.

10.4. Main results

The main effectiveness endpoints are provided for the FAS overall and by country, in In-text Table 5. Although results are presented both overall and by country, due to the small number of respondents, results by country will not be discussed. The corresponding source tables for the FAS and CAS are provided in Section 15, Table 5 and Table 6, respectively.

Although only about half (48.7%) of respondents acknowledged awareness of the XALKORI PIB, approximately three-quarters acknowledged receipt of (76.9%) of the PIB. Among respondents who received the PIB, 93.3% of them reported reading the PIB and approximately half (46.7%) of them reported that they knew about the patient ID card. Among respondents who were aware of the patient ID card, 21.4% reported using the patient ID card.

Knowledge of the side effects associated with XALKORI ranged from 35.9% to 84.6%. The majority of respondents had knowledge of "changes to vision" (84.6%), "dizziness, light-headedness, fainting, tiredness" (69.2%), and "abnormalities in liver blood tests" (61.5%). Approximately half (48.7%) of respondents were aware XALKORI may cause "chest discomfort or irregular heartbeat". Approximately one-third of respondents were aware XALKORI may cause "slow in heart rate" (38.5%) or "breathing problems" (35.9%).

In general, knowledge of precautions for use of XALKORI was higher than knowledge of side effects. Approximately two-thirds of respondents knew they may need to stop driving/operating machinery for vision changes (66.7%) and to inform their doctor of persistent or worsening changes to vision (69.2%). More than half (56.4%) of respondents knew their doctor would monitor their heart function and may adjust their XALKORI dosage.

Knowledge of reasons to call your doctor ranged from 53.8% to 84.6%. Specifically, knowledge rates to call your doctor for "light-headedness, chest discomfort, fainting" and "difficulties with breathing, cough, fever" were both 84.6%. About seventy-four percent (74.4%) of respondents knew to call their doctor for "nausea, vomiting", 66.7% knew to call their doctor for "skin and whites of your eyes turn yellow", 56.4% knew to call their doctor for "urine turns dark or brown (tea colour)", and 53.8% knew to call their doctor for "itching, or bruised more easily than usual".

In-text Table 5. Effectiveness of the XALKORI PIB Overall and by Country – Full Analysis Set (Page 1 of 3)

	Overall N=39	Austria n=2	Belgium n=5	France n=1	Germany n=9	Italy n=17	Netherlands n=1	Sweden n=4
Awareness of the XALKORI PIB and the patient ID card included in the PIB (n [%])								
Awareness of the XALKORI PIB (Q4)								
n (%)	19 (48.7)	2 (100.0)	1 (20.0)	0 (0.0)	5 (55.6)	9 (52.9)	0 (0.0)	2 (50.0)
95% CI	[32.4; 65.2]	[15.8; 100.0]	[0.5; 71.6]	[0.0; 97.5]	[21.2; 86.3]	[27.8; 77.0]	[0.0; 97.5]	[6.8; 93.2]
Receipt of the XALKORI PIB (Q5)								
n (%)	30 (76.9)	2 (100.0)	2 (40.0)	0 (0.0)	7 (77.8)	16 (94.1)	0 (0.0)	3 (75.0)
95% CI	[60.7; 88.9]	[15.8; 100.0]	[5.3; 85.3]	[0.0; 97.5]	[40.0; 97.2]	[71.3; 99.9]	[0.0; 97.5]	[19.4; 99.4]
Awareness of the patient ID card (Q13)[a]								
n (%)	14 (46.7)	1 (50.0)	2 (100.0)	0 (0.0)	5 (71.4)	5 (31.3)	0 (0.0)	1 (33.3)
95% CI	[28.3; 65.7]	[1.3; 98.7]	[15.8; 100.0]	[0.0; 97.5]	[29.0; 96.3]	[11.0; 58.7]	[0.0; 97.5]	[0.8; 90.6]
Utilisation of the PIB								
Utilisation of the XALKORI PIB (Q7)[a]								
n (%)	28 (93.3)	1 (50.0)	2 (100.0)	0 (0.0)	7 (100.0)	15 (93.8)	0 (0.0)	3 (100.0)
95% CI	[77.9; 99.2]	[1.3; 98.7]	[15.8; 100.0]	[0.0; 97.5]	[59.0; 100.0]	[69.8; 99.8]	[0.0; 97.5]	[29.2; 100.0]
Utilisation of the XALKORI patient ID card (Q14)[b]								
n (%)	3 (21.4)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (40.0)	0 (0.0)	0 (0.0)
95% CI	[4.7; 50.8]	[2.5; 100.0]	[0.0; 84.2]	[0.0; 97.5]	[0.0; 52.2]	[5.3; 85.3]	[0.0; 97.5]	[0.0; 97.5]
Knowledge/comprehension of the risks (n [%])								
Side effect: Breathing problems (Q1A)								
n (%)	14 (35.9)	1 (50.0)	1 (20.0)	1 (100.0)	3 (33.3)	5 (29.4)	0 (0.0)	3 (75.0)
95% CI	[21.2; 52.8]	[1.3; 98.7]	[0.5; 71.6]	[2.5; 100.0]	[7.5; 70.1]	[10.3; 56.0]	[0.0; 97.5]	[19.4; 99.4]
Side effect: Abnormalities in liver blood tests (Q1B)								
n (%)	24 (61.5)	1 (50.0)	3 (60.0)	0 (0.0)	7 (77.8)	9 (52.9)	0 (0.0)	4 (100.0)
95% CI	[44.6; 76.6]	[1.3; 98.7]	[14.7; 94.7]	[0.0; 97.5]	[40.0; 97.2]	[27.8; 77.0]	[0.0; 97.5]	[39.8; 100.0]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)								
n (%)	27 (69.2)	1 (50.0)	2 (40.0)	1 (100.0)	8 (88.9)	11 (64.7)	0 (0.0)	4 (100.0)
95% CI	[52.5; 83.0]	[1.3; 98.7]	[5.3; 85.3]	[2.5; 100.0]	[51.8; 99.7]	[38.3; 85.8]	[0.0; 97.5]	[39.8; 100.0]
Side effect: Chest discomfort or irregular heartbeat (Q1F)								
n (%)	19 (48.7)	0 (0.0)	0 (0.0)	0 (0.0)	6 (66.7)	10 (58.8)	0 (0.0)	3 (75.0)
95% CI	[32.4; 65.2]	[0.0; 84.2]	[0.0; 52.2]	[0.0; 97.5]	[29.9; 92.5]	[32.9; 81.6]	[0.0; 97.5]	[19.4; 99.4]
Side effect: Changes to vision (Q1G)								

In-text Table 5. Effectiveness of the XALKORI PIB Overall and by Country – Full Analysis Set (Page 2 of 3)

	Overall N=39	Austria n=2	Belgium n=5	France n=1	Germany n=9	Italy n=17	Netherlands n=1	Sweden n=4
n (%)	33 (84.6)	1 (50.0)	3 (60.0)	1 (100.0)	8 (88.9)	16 (94.1)	0 (0.0)	4 (100.0)
95% CI	[69.5; 94.1]	[1.3; 98.7]	[14.7; 94.7]	[2.5; 100.0]	[51.8; 99.7]	[71.3; 99.9]	[0.0; 97.5]	[39.8; 100.0]
Side effect: Slow in heart rate (Q1H)								
n (%)	15 (38.5)	1 (50.0)	0 (0.0)	1 (100.0)	4 (44.4)	7 (41.2)	0 (0.0)	2 (50.0)
95% CI	[23.4; 55.4]	[1.3; 98.7]	[0.0; 52.2]	[2.5; 100.0]	[13.7; 78.8]	[18.4; 67.1]	[0.0; 97.5]	[6.8; 93.2]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A) (n [%])								
n (%)	26 (66.7)	1 (50.0)	1 (20.0)	1 (100.0)	7 (77.8)	13 (76.5)	0 (0.0)	3 (75.0)
95% CI	[49.8; 80.9]	[1.3; 98.7]	[0.5; 71.6]	[2.5; 100.0]	[40.0; 97.2]	[50.1; 93.2]	[0.0; 97.5]	[19.4; 99.4]
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B) (n [%])								
n (%)	27 (69.2)	1 (50.0)	5 (100.0)	1 (100.0)	4 (44.4)	11 (64.7)	1 (100.0)	4 (100.0)
95% CI	[52.5; 83.0]	[1.3; 98.7]	[47.8; 100.0]	[2.5; 100.0]	[13.7; 78.8]	[38.3; 85.8]	[2.5; 100.0]	[39.8; 100.0]
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C) (n [%])								
n (%)	22 (56.4)	1 (50.0)	1 (20.0)	0 (0.0)	7 (77.8)	9 (52.9)	0 (0.0)	4 (100.0)
95% CI	[39.6 72.2]	[1.3; 98.7]	[0.5; 71.6]	[0.0; 97.5]	[40.0; 97.2]	[27.8; 77.0]	[0.0; 97.5]	[39.8; 100.0]
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A) (n [%])								
n (%)	33 (84.6)	2 (100.0)	2 (40.0)	1 (100.0)	9 (100.0)	15 (88.2)	0 (0.0)	4 (100.0)
95% CI	[69.5; 94.1]	[15.8; 100.0]	[5.3; 85.3]	[2.5; 100.0]	[66.4; 100.0]	[63.6; 98.5]	[0.0; 97.5]	[39.8; 100.0]
Call your doctor: Skin and whites of your eyes turn yellow (Q3B) (n [%])								
n (%)	26 (66.7)	2 (100.0)	3 (60.0)	1 (100.0)	6 (66.7)	10 (58.8)	0 (0.0)	4 (100.0)
95% CI	[49.8; 80.9]	[15.8; 100.0]	[14.7; 94.7]	[2.5; 100.0]	[29.9; 92.5]	[32.9; 81.6]	[0.0; 97.5]	[39.8; 100.0]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C) (n [%])								
n (%)	22 (56.4)	0 (0.0)	2 (40.0)	1 (100.0)	5 (55.6)	9 (52.9)	1 (100.0)	4 (100.0)
95% CI	[39.6 72.2]	[0.0; 84.2]	[5.3; 85.3]	[2.5; 100.0]	[21.2; 86.3]	[27.8; 77.0]	[2.5; 100.0]	[39.8; 100.0]
Call your doctor: Nausea, vomiting (Q3D (n [%])**)**								
n (%)	29 (74.4)	0 (0.0)	4 (80.0)	1 (100.0)	9 (100.0)	12 (70.6)	1 (100.0)	2 (50.0)
95% CI	[57.9; 87.0]	[0.0; 84.2]	[28.4; 99.5]	[2.5; 100.0]	[66.4; 100.0]	[44.0; 89.7]	[2.5; 100.0]	[6.8; 93.2]

In-text Table 5. Effectiveness of the XALKORI PIB Overall and by Country – Full Analysis Set (Page 3 of 3)

	Overall N=39	Austria n=2	Belgium n=5	France n=1	Germany n=9	Italy n=17	Netherlands n=1	Sweden n=4
Call your doctor: Difficulties with breathing, cough, fever (Q3E) (n [%])								
n (%)	33 (84.6)	2 (100.0)	4 (80.0)	1 (100.0)	8 (88.9)	13 (76.5)	1 (100.0)	4 (100.0)
95% CI	[69.5; 94.1]	[15.8; 100.0]	[28.4; 99.5]	[2.5; 100.0]	[51.8; 99.7]	[50.1; 93.2]	[2.5; 100.0]	[39.8; 100.0]
Call your doctor: Itching, or bruised more easily than usual (Q3F) (n [%])								
n (%)	21 (53.8)	2 (100.0)	1 (20.0)	1 (100.0)	6 (66.7)	8 (47.1)	1 (100.0)	2 (50.0)
95% CI	[37.2; 69.9]	[15.8; 100.0]	[0.5; 71.6]	[2.5; 100.0]	[29.9; 92.5]	[23.0; 72.2]	[2.5; 100.0]	[6.8; 93.2]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
CI=confidence interval, ID=identification, PIB=Patient Information Brochure
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5)
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13)
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

In Figure 1-Figure 3, the main effectiveness endpoints are provided for the FAS by PIB reading status; Section 15, Tables 6-9 provide these same results in tabular format for the FAS and CAS, respectively. Figure 1 shows a clear trend of increased knowledge rates across all questions related to risks associated with XALKORI for respondents who read the PIB in comparison with respondents who did not read or receive the PIB. Specifically, for respondents who read vs. did not read or receive the PIB, knowledge rates were 39.3% vs. 27.3% for breathing problems, 64.3% vs. 54.5% for abnormal liver blood tests, 78.6% vs. 45.5% for dizziness, light-headedness, fainting, tiredness, 57.1% vs. 27.3% for chest discomfort or irregular heartbeat, 96.4% vs. 54.5% for changes to vision, and 42.9% vs. 27.3% for slow heart rate. Figure 2 shows a similar trend of increased knowledge rates across most questions concerning precautions for use of XALKORI for respondents who read the PIB in comparison with respondents who did not read or receive the PIB. Knowledge rates for respondents who read vs. did not read or receive the PIB were 75.0% vs. 45.5% for "may need to stop driving/operating machinery for vision changes" and 64.3% vs. 36.4% for "doctor will monitor your heart function and may need to adjust your XALKORI dosage", although knowledge rates of the need to inform your doctor of vision changes was similar regardless of having read the PIB (67.9% vs. 72.7%). In Figure 3, no trend of a difference (i.e., a consistent increase or decrease) in knowledge rates across all questions regarding reasons to call your doctor by reading status is observed – for 3 of the 6 reasons to call your doctor (light-headedness/chest discomfort/fainting, skin and whites of your eyes turn yellow, urine turns dark or brown/tea colour), knowledge rates were higher for patients who read the PIB; for the other 3 reasons to call your doctor (nausea/vomiting, difficulties with breathing/cough/fever, itching or bruised more easily than usual) knowledge rates were slightly higher for patients who had not read or received the PIB.

Figure 1. Effectiveness of the XALKORI PIB (Knowledge of Side Effects), by PIB Reading Status – Full Analysis Set

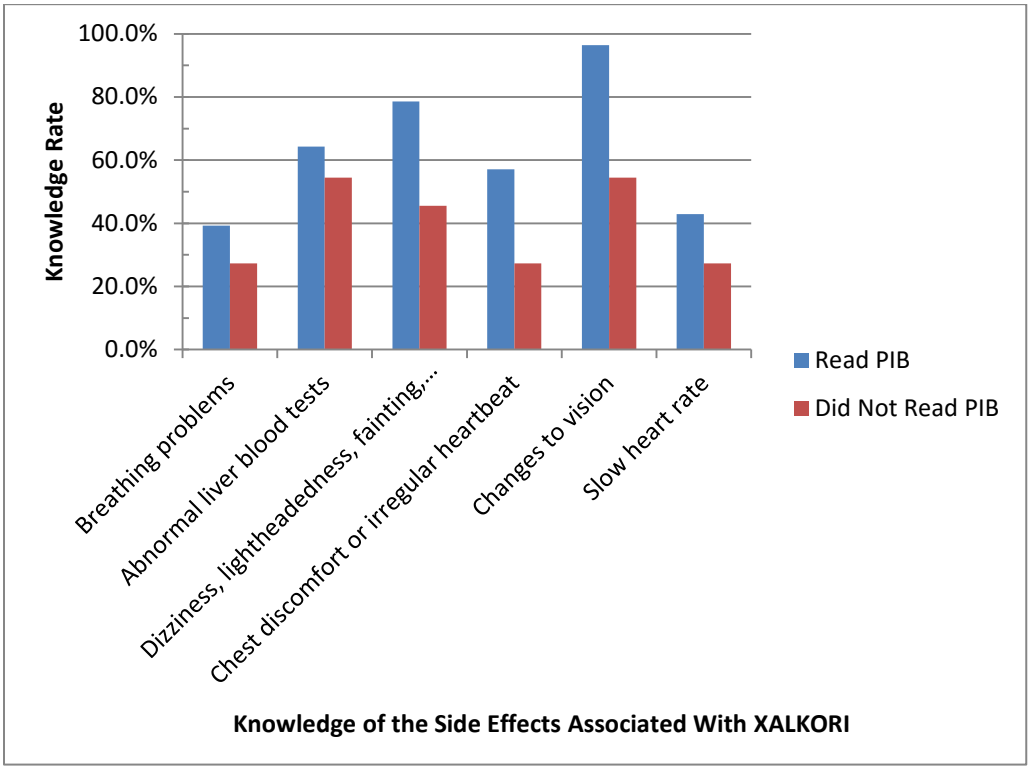


Figure 2. Effectiveness of the XALKORI PIB (Knowledge of Precautions for Use), by PIB Reading Status – Full Analysis Set

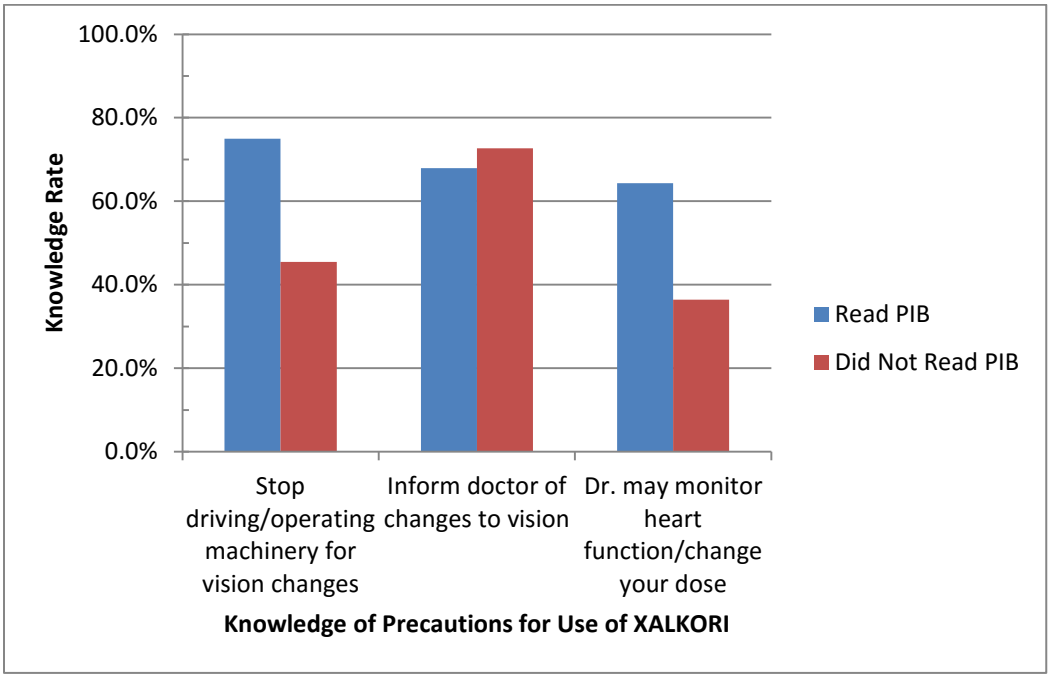


Figure 3. Effectiveness of the XALKORI PIB (Knowledge of Reasons to Call Your Doctor), by PIB Reading Status – Full Analysis Set

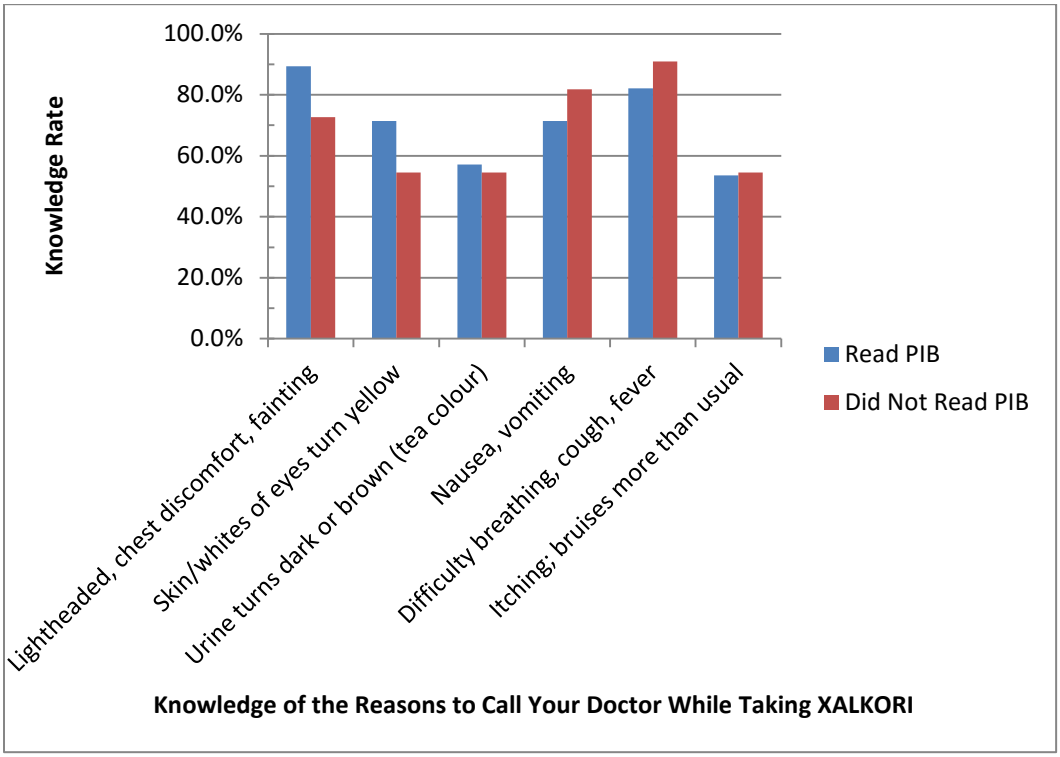
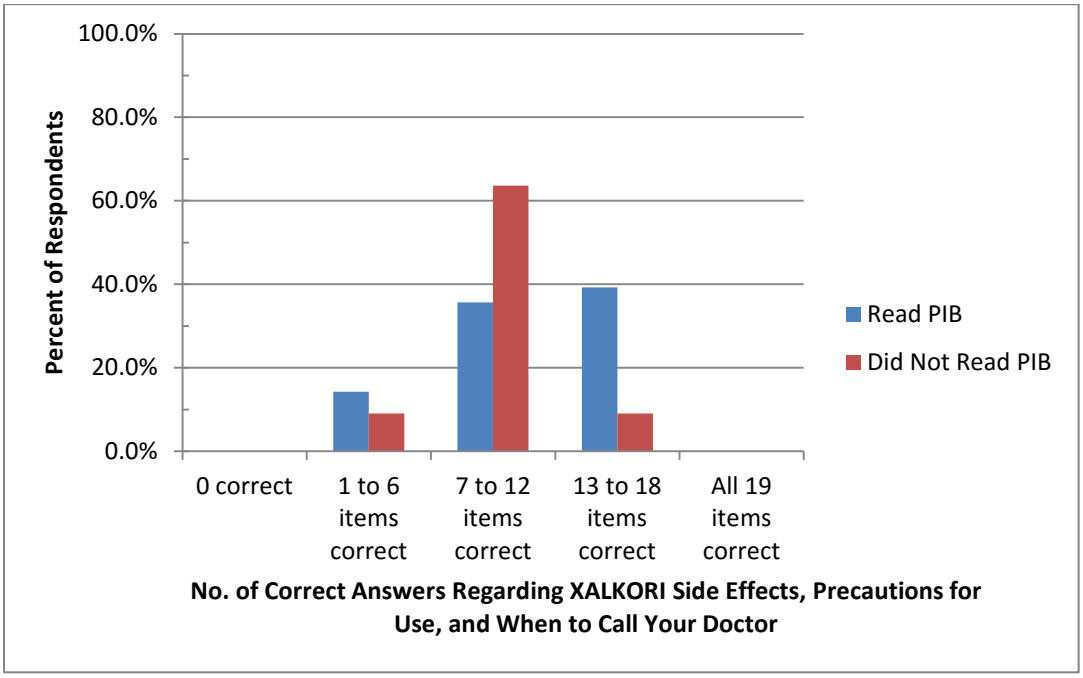


Figure 4 provides a composite view of the main effectiveness endpoints for the FAS by PIB reading status; the corresponding composite endpoint results in tabular format for the FAS and CAS are provided in Section 15, Tables 8 and 9. Respondents who read the PIB were able to answer more questions correctly than respondents who did not read or receive the PIB; for example, the percentage of respondents who answered 13 to 18 items of the 19 total items correctly was 39.3% for respondents who read the PIB vs. 9.1% for respondents did not read or receive the PIB.

Figure 4. Composite Endpoint of Knowledge of Side Effects, Precautions for Use, and When to Call Your Doctor, by PIB Reading Status – Full Analysis Set



Results by age and education level for both the FAS and CAS are provided in Section 15, Tables 10–13. Because the majority of patients (76.9%) were <65 years old, results by age group were not meaningful due to the small number of patients (n=9) in the older age group.

Awareness and receipt of the XALKORI PIB and patient ID card was lower for respondents with university/higher education levels in comparison with respondents who had completed only primary or secondary school (Section 15, Tables 12–13). However, among respondents who had received these materials, reading of the PIB was high and did not vary by education level. Use of the patient ID card was too low (n=3) to interpret differences by education level. For most (but not all) questions about side effects, precautions for use, and when to call your doctor, knowledge rates were highest for respondents who had completed only primary school, lowest for respondents who had completed up through secondary school, and in the middle for respondents with university/higher education. However, the number of respondents in each of the subgroups is low, so these results should be interpreted with caution.

10.5. Other analyses

The distribution of responses to all answer choices to all survey questions are provided for both the FAS and CAS in Section 15, Tables 14–21.

10.6. Adverse events / adverse reactions

This study was a survey conducted among XALKORI-treated patients to evaluate the effectiveness of the XALKORI PIB implemented in the EU. The study did not involve data collection on clinical endpoints for individual patients, and information on safety events for

individual patients was not solicited on the survey questionnaire. However, safety information may be identified during the course of data collection. Any safety information for an individual patient that was volunteered by a study participant during the course of this research was to be reported. Study staff completed the Pfizer-required training "Your Reporting Responsibilities: Monitoring the Safety, Performance, and Quality of Pfizer Products (Multiple Languages)", and any relevant "Your Reporting Responsibilities" supplemental training, prior to commencement of the study. All training was recorded and copies of all signed training certifications are maintained in study files.

The survey questionnaire had a small number of questions which included the option to record open text responses, and was also available to complete on paper. As a result, although unlikely, a survey respondent could have used one of these open text fields or margins on the paper to report an AE. In the event that a study participant reported a safety event associated with a Pfizer product, Mapi was to complete the NIS AEM Report Form and submit to Pfizer within 24 hours of awareness, enabling the event to be processed according to Pfizer's standard operating procedures.

Throughout the survey conduct, all surveys received on paper, and all results recorded in any open text fields, were reviewed to identify any reported AEs. No AEs were reported by any survey respondent throughout the entire study conduct.

11. DISCUSSION

11.1. Key results

In this study, rates of receipt and reading of the PIB were high. The majority of respondents acknowledged receipt of and reading the PIB (76.9% and 93.3%, respectively). Among respondents who reported receiving the PIB, approximately half (46.7%) acknowledged they knew about the patient ID card, and of those who were aware of the patient ID card, 21.4% reported using the patient ID card.

Knowledge of the side effects, precautions for use, and reasons to call your doctor was high for several XALKORI-associated risks. In particular, knowledge of the risk of changes in vision was 84.6%, and knowledge rates for 2 vision-related precautions for use were 66.7% and 69.2%. Additionally, knowledge of risks related to hepatotoxicity was 61.5%, and knowledge of dizziness/light-headedness/fainting/tiredness was 69.2%. However, less than half of respondents were aware XALKORI may cause "chest discomfort or irregular heartbeat", "slow in heart rate", or "breathing problems".

Knowledge rates were consistently higher for respondents who read the PIB in comparison with respondents who did not read or receive the PIB.

11.2. Limitations

Given the rarity of ALK-positive NSCLC, it is expected that the number of physicians prescribing XALKORI is low. For this study, the main challenges in recruitment were largely due to both the small number of treating physicians who were actually interested and/or engaged in identifying patients to participate in the survey, and feasibility constraints such as inordinately lengthy processes for IEC approvals in some countries due to a general

lack of experience of ethics committees with surveys to evaluate effectiveness of educational materials. Therefore, the precision of the knowledge rate estimates in the study is low due to a small number of patients completing the survey (n=39).

The primary limitation of this cross-sectional study was selection bias due to use of a convenience sample and the low response rate. Efforts were made to minimize the impact of selection bias through carefully considering country selection to include countries where XALKORI prescribing rates were highest and also to obtain a diverse European sample by including countries from various regions of the EU. From the outset, it was still probable that the patient sample would be susceptible to selection bias. However, the impact of this cannot be specifically quantified.

Knowledge rates in this study may also have been subject to information bias. Specifically, differential misclassification bias was likely a concern for the 7 questions regarding "for which of the following should you call your doctor right away while taking XALKORI". For all 7 questions, most respondents checked "yes", regardless of whether the listed problem was included in the PIB or not. Patients may be likely to call their doctor for any of the listed problems, regardless of an association with their XALKORI treatment. In hindsight, these particular 7 questions may have better reflected knowledge of the information in the PIB if the question had been worded as "for which of the following does the XALKORI PIB recommend for you to call your doctor right away while taking XALKORI".

The objective of this study was to evaluate the effectiveness of the PIB. However, information contained in the XALKORI PIB is similar to information included in the Patient Information Leaflet (PIL). Therefore, it is challenging to separate the effectiveness of the PIB from that of the PIL.

11.3. Interpretation

Rates of receipt and reading of the PIB were high; however, awareness of the PIB and the patient ID card was lower. It is difficult to interpret this result. It should be noted that more than half of patients indicating they were not aware of the PIB subsequently reported they had received the PIB. Among respondents who reported receiving the PIB, approximately half of respondents acknowledged they knew about the patient ID card, and about a quarter of those who were aware of the patient ID card reported using the patient ID card. Since patients with advanced stage cancer are often treated at large academic-affiliated hospitals or cancer centres, it is possible that the patient ID card is less useful in this type of setting, as patients' cancer care is often already well-coordinated across a variety of healthcare professionals and the need to use the ID card to alert other providers may not be necessary.

Knowledge of the side effects, precautions for use, and reasons to call your doctor was high for several XALKORI-associated risks; however, knowledge rates that XALKORI may cause "chest discomfort or irregular heartbeat", "slow in heart rate", or "breathing problems" revealed some gaps. This lower knowledge for certain risks associated with XALKORI could constitute an increased risk if patients are not aware that they need to watch for these specific risks.

Knowledge rates were consistently increased for respondents who read the PIB in comparison with respondents who did not read or receive the PIB. It seems that the PIB may be an effective channel for communicating information on risks associated with XALKORI.

11.4. Generalisability

The 10 EU countries that participated in this study were specifically selected in an endeavour to obtain a representative sample of patients receiving XALKORI in the EU. However, due to the small number of respondents, including for several countries where only 5 or fewer patients treated at only a few number of centres completed the survey, caution should be used in generalising the results to all patients in the EU.

12. OTHER INFORMATION

Not applicable.

13. CONCLUSIONS

The results of this survey indicate that the XALKORI PIB was received and read by the majority of survey respondents. In addition, knowledge rates of XALKORI side effects, precautions for use, and reasons to call your doctor indicated that the majority of survey respondents were aware of most of this information, and knowledge rates were consistently higher for respondents who read the PIB in comparison with respondents who did not read or receive the PIB. Knowledge rates for some risks revealed some gaps. Based on the results of the survey, it appears that the PIB is an effective channel for communicating information to patients on risks associated with XALKORI.

14. REFERENCES

1. http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx.

2. Jemal A, Bray F, Center MM, Ferlay J, Ward E, Forman D. Global cancer statistics. CA: a cancer journal for clinicians 2011;61(2):69-90.(85% NSCLC).

3. Varella-Garcia M, Cho Y, Lu X, et al. ALK gene rearrangements in unselected caucasians with non-small cell lung carcinoma (NSCLC). J Clin Oncol (Meeting Abstracts) 2010; 28 (15 suppl (May 20 Supplement)):10533.

4. PASS version 2008.0.5, NCSS, LLC, 329 North 1000 East, Kaysville, UT 84037.

15. LIST OF SOURCE TABLES

Table 1: Patient Disposition Overall and by Country

	Overall N=40	Austria N=2	Belgium N=5	Denmark N=0	France N=1	Germany N=9	Ireland N=0	Italy N=18	Netherlands N=1	Sweden N=4	United Kingdom N=0
Survey modality											
Paper	36 (90.0%)	2 (100.0%)	4 (80.0%)	0 (0.0%)	1 (100.0%)	9 (100.0%)	0 (0.0%)	16 (88.9%)	1 (100.0%)	3 (75.0%)	0 (0.0%)
On-line	4 (10.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (11.1%)	0 (0.0%)	1 (25.0%)	0 (0.0%)
Eligible											
Yes	39 (97.5%)	2 (100.0%)	5 (100.0%)	0 (0.0%)	1 (100.0%)	9 (100.0%)	0 (0.0%)	17 (94.4%)	1 (100.0%)	4 (100.0%)	0 (0.0%)
No	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If no: reasons for exclusion											
Not agree to take part in this survey	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Patient not treated with at least one dose of XALKORI within the past 90 days	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Participation in a pre-testing survey	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Self or family members employed by Pfizer, Mapi, or EMA in the past 10 years	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Survey status											
Only completed some/all eligibility questions	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Completed at least 1 main question[a]	39 (100.0%)	2 (100.0%)	5 (100.0%)	0 (0.0%)	1 (100.0%)	9 (100.0%)	0 (0.0%)	17 (100.0%)	1 (100.0%)	4 (100.0%)	0 (0.0%)
Completed all core questions[b]	34 (87.2%)	2 (100.0%)	5 (100.0%)	0 (0.0%)	1 (100.0%)	7 (77.8%)	0 (0.0%)	14 (82.4%)	1 (100.0%)	4 (100.0%)	0 (0.0%)
Analysis Sets											
Full analysis set (Eligible patients who have completed at least 1 main survey question)	39 (97.5%)	2 (100.0%)	5 (100.0%)	0 (0.0%)	1 (100.0%)	9 (100.0%)	0 (0.0%)	17 (94.4%)	1 (100.0%)	4 (100.0%)	0 (0.0%)
Completer analysis set (Eligible patients who have completed all core survey questions)	34 (85.0%)	2 (100.0%)	5 (100.0%)	0 (0.0%)	1 (100.0%)	7 (77.8%)	0 (0.0%)	14 (77.8%)	1 (100.0%)	4 (100.0%)	0 (0.0%)

MD=Missing data

[a] Main survey questions= questions 1-14 (Variable described among the eligible population).

[b] Core survey questions= questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13 (Variable described among the eligible population).

Table 2: Patient Characteristics Overall and by Country - Full Analysis Set

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Last time treated with XALKORI								
Within the last month	32 (82.1%)	2 (100.0%)	3 (60.0%)	1 (100.0%)	7 (77.8%)	14 (82.4%)	1 (100.0%)	4 (100.0%)
1 month ago	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (5.9%)	0 (0.0%)	0 (0.0%)
2 months ago	3 (7.7%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months ago	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (11.8%)	0 (0.0%)	0 (0.0%)
I don’t know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Current participant in a XALKORI clinical trial								
Yes	11 (28.2%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	2 (22.2%)	7 (41.2%)	1 (100.0%)	0 (0.0%)
No	22 (56.4%)	2 (100.0%)	3 (60.0%)	0 (0.0%)	6 (66.7%)	7 (41.2%)	0 (0.0%)	4 (100.0%)
I don't know	6 (15.4%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	1 (11.1%)	3 (17.6%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gender								
Male	11 (28.2%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	3 (33.3%)	5 (29.4%)	0 (0.0%)	0 (0.0%)
Female	28 (71.8%)	2 (100.0%)	2 (40.0%)	1 (100.0%)	6 (66.7%)	12 (70.6%)	1 (100.0%)	4 (100.0%)
Prefer not to answer	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Age group								
18-44	9 (23.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	7 (41.2%)	0 (0.0%)	1 (25.0%)
45-54	8 (20.5%)	2 (100.0%)	1 (20.0%)	0 (0.0%)	3 (33.3%)	2 (11.8%)	0 (0.0%)	0 (0.0%)
55-64	13 (33.3%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	3 (33.3%)	5 (29.4%)	0 (0.0%)	2 (50.0%)
65-74	7 (17.9%)	0 (0.0%)	1 (20.0%)	1 (100.0%)	2 (22.2%)	2 (11.8%)	0 (0.0%)	1 (25.0%)
75 or older	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (100.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Educational level								
Primary School	7 (17.9%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (35.3%)	0 (0.0%)	0 (0.0%)
Secondary School	11 (28.2%)	0 (0.0%)	4 (80.0%)	0 (0.0%)	2 (22.2%)	5 (29.4%)	0 (0.0%)	0 (0.0%)
University/Higher Education	13 (33.3%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	0 (0.0%)	6 (35.3%)	1 (100.0%)	3 (75.0%)
Prefer not to Answer	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
MD	7 (17.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (77.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient surveyMD=Missing data

Table 3: Patient Characteristics Overall and by Country - Completer Analysis Set

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Last time treated with XALKORI								
Within the last month	28 (82.4%)	2 (100.0%)	3 (60.0%)	1 (100.0%)	5 (71.4%)	12 (85.7%)	1 (100.0%)	4 (100.0%)
1 month ago	2 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)
2 months ago	3 (8.8%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
3 months ago	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)
I don’t know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Current participant in a XALKORI clinical trial								
Yes	8 (23.5%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (14.3%)	5 (35.7%)	1 (100.0%)	0 (0.0%)
No	21 (61.8%)	2 (100.0%)	3 (60.0%)	0 (0.0%)	5 (71.4%)	7 (50.0%)	0 (0.0%)	4 (100.0%)
I don't know	5 (14.7%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	1 (14.3%)	2 (14.3%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Gender								
Male	10 (29.4%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	2 (28.6%)	5 (35.7%)	0 (0.0%)	0 (0.0%)
Female	24 (70.6%)	2 (100.0%)	2 (40.0%)	1 (100.0%)	5 (71.4%)	9 (64.3%)	1 (100.0%)	4 (100.0%)
Prefer not to answer	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Age group								
18-44	8 (23.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	6 (42.9%)	0 (0.0%)	1 (25.0%)
45-54	8 (23.5%)	2 (100.0%)	1 (20.0%)	0 (0.0%)	3 (42.9%)	2 (14.3%)	0 (0.0%)	0 (0.0%)
55-64	9 (26.5%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	1 (14.3%)	3 (21.4%)	0 (0.0%)	2 (50.0%)
65-74	7 (20.6%)	0 (0.0%)	1 (20.0%)	1 (100.0%)	2 (28.6%)	2 (14.3%)	0 (0.0%)	1 (25.0%)
75 or older	2 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (100.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Educational level								
Primary School	5 (14.7%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (28.6%)	0 (0.0%)	0 (0.0%)
Secondary School	9 (26.5%)	0 (0.0%)	4 (80.0%)	0 (0.0%)	1 (14.3%)	4 (28.6%)	0 (0.0%)	0 (0.0%)
University/Higher Education	13 (38.2%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	0 (0.0%)	6 (42.9%)	1 (100.0%)	3 (75.0%)
Prefer not to Answer	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
MD	6 (17.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (85.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data

Table 4: Effectiveness of the XALKORI Patient Information Brochure (PIB) Overall and by Country - Full Analysis Set (page 1 of 3)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Awareness of the XALKORI PIB and the patient ID card included in the PIB								
Awareness of the XALKORI PIB (Q4)								
n (%)	19 (48.7%)	2 (100.0%)	1 (20.0%)	0 (0.0%)	5 (55.6%)	9 (52.9%)	0 (0.0%)	2 (50.0%)
95% CI	[32.4%;65.2%]	[15.8%;100.0%]	[0.5%;71.6%]	[0.0%;97.5%]	[21.2%;86.3%]	[27.8%;77.0%]	[0.0%;97.5%]	[6.8%;93.2%]
Receipt of the XALKORI PIB (Q5)								
n (%)	30 (76.9%)	2 (100.0%)	2 (40.0%)	0 (0.0%)	7 (77.8%)	16 (94.1%)	0 (0.0%)	3 (75.0%)
95% CI	[60.7%;88.9%]	[15.8%;100.0%]	[5.3%;85.3%]	[0.0%;97.5%]	[40.0%;97.2%]	[71.3%;99.9%]	[0.0%;97.5%]	[19.4%;99.4%]
Awareness of the patient ID card (Q13)[a]								
n (%)	14 (46.7%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	5 (71.4%)	5 (31.3%)	0 (0.0%)	1 (33.3%)
95% CI	[28.3%;65.7%]	[1.3%;98.7%]	[15.8%;100.0%]		[29.0%;96.3%]	[11.0%;58.7%]		[0.8%;90.6%]
Utilisation of the PIB								
Utilisation of the XALKORI PIB (Q7)[a]								
n (%)	28 (93.3%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	7 (100.0%)	15 (93.8%)	0 (0.0%)	3 (100.0%)
95% CI	[77.9%;99.2%]	[1.3%;98.7%]	[15.8%;100.0%]		[59.0%;100.0%]	[69.8%;99.8%]		[29.2%;100.0%]
Utilisation of the XALKORI patient ID card (Q14)[b]								
n (%)	3 (21.4%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)
95% CI	[4.7%;50.8%]	[2.5%;100.0%]	[0.0%;84.2%]		[0.0%;52.2%]	[5.3%;85.3%]		[0.0%;97.5%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 4: Effectiveness of the XALKORI Patient Information Brochure (PIB) Overall and by Country - Full Analysis Set (page 2 of 3)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Knowledge/comprehension of the risks[c]								
Side effect: Breathing problems (Q1A)								
n (%)	14 (35.9%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	3 (33.3%)	5 (29.4%)	0 (0.0%)	3 (75.0%)
95% CI	[21.2%;52.8%]	[1.3%;98.7%]	[0.5%;71.6%]	[2.5%;100.0%]	[7.5%;70.1%]	[10.3%;56.0%]	[0.0%;97.5%]	[19.4%;99.4%]
Side effect: Abnormalities in liver blood tests (Q1B)								
n (%)	24 (61.5%)	1 (50.0%)	3 (60.0%)	0 (0.0%)	7 (77.8%)	9 (52.9%)	0 (0.0%)	4 (100.0%)
95% CI	[44.6%;76.6%]	[1.3%;98.7%]	[14.7%;94.7%]	[0.0%;97.5%]	[40.0%;97.2%]	[27.8%;77.0%]	[0.0%;97.5%]	[39.8%;100.0%]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)								
n (%)	27 (69.2%)	1 (50.0%)	2 (40.0%)	1 (100.0%)	8 (88.9%)	11 (64.7%)	0 (0.0%)	4 (100.0%)
95% CI	[52.4%;83.0%]	[1.3%;98.7%]	[5.3%;85.3%]	[2.5%;100.0%]	[51.8%;99.7%]	[38.3%;85.8%]	[0.0%;97.5%]	[39.8%;100.0%]
Side effect: Chest discomfort or irregular heartbeat (Q1F)								
n (%)	19 (48.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (66.7%)	10 (58.8%)	0 (0.0%)	3 (75.0%)
95% CI	[32.4%;65.2%]	[0.0%;84.2%]	[0.0%;52.2%]	[0.0%;97.5%]	[29.9%;92.5%]	[32.9%;81.6%]	[0.0%;97.5%]	[19.4%;99.4%]
Side effect: Changes to vision (Q1G)								
n (%)	33 (84.6%)	1 (50.0%)	3 (60.0%)	1 (100.0%)	8 (88.9%)	16 (94.1%)	0 (0.0%)	4 (100.0%)
95% CI	[69.5%;94.1%]	[1.3%;98.7%]	[14.7%;94.7%]	[2.5%;100.0%]	[51.8%;99.7%]	[71.3%;99.9%]	[0.0%;97.5%]	[39.8%;100.0%]
Side effect: Slow in heart rate (Q1H)								
n (%)	15 (38.5%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	4 (44.4%)	7 (41.2%)	0 (0.0%)	2 (50.0%)
95% CI	[23.4%;55.4%]	[1.3%;98.7%]	[0.0%;52.2%]	[2.5%;100.0%]	[13.7%;78.8%]	[18.4%;67.1%]	[0.0%;97.5%]	[6.8%;93.2%]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A)								
n (%)	26 (66.7%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	7 (77.8%)	13 (76.5%)	0 (0.0%)	3 (75.0%)
95% CI	[49.8%;80.9%]	[1.3%;98.7%]	[0.5%;71.6%]	[2.5%;100.0%]	[40.0%;97.2%]	[50.1%;93.2%]	[0.0%;97.5%]	[19.4%;99.4%]
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B)								
n (%)	27 (69.2%)	1 (50.0%)	5 (100.0%)	1 (100.0%)	4 (44.4%)	11 (64.7%)	1 (100.0%)	4 (100.0%)
95% CI	[52.4%;83.0%]	[1.3%;98.7%]	[47.8%;100.0%]	[2.5%;100.0%]	[13.7%;78.8%]	[38.3%;85.8%]	[2.5%;100.0%]	[39.8%;100.0%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 4: Effectiveness of the XALKORI Patient Information Brochure (PIB) Overall and by Country - Full Analysis Set (page 3 of 3)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)								
n (%)	22 (56.4%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	7 (77.8%)	9 (52.9%)	0 (0.0%)	4 (100.0%)
95% CI	[39.6%;72.2%]	[1.3%;98.7%]	[0.5%;71.6%]	[0.0%;97.5%]	[40.0%;97.2%]	[27.8%;77.0%]	[0.0%;97.5%]	[39.8%;100.0%]
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A)								
n (%)	33 (84.6%)	2 (100.0%)	2 (40.0%)	1 (100.0%)	9 (100.0%)	15 (88.2%)	0 (0.0%)	4 (100.0%)
95% CI	[69.5%;94.1%]	[15.8%;100.0%]	[5.3%;85.3%]	[2.5%;100.0%]	[66.4%;100.0%]	[63.6%;98.5%]	[0.0%;97.5%]	[39.8%;100.0%]
Call your doctor: Skin and whites of your eyes turn yellow (Q3B)								
n (%)	26 (66.7%)	2 (100.0%)	3 (60.0%)	1 (100.0%)	6 (66.7%)	10 (58.8%)	0 (0.0%)	4 (100.0%)
95% CI	[49.8%;80.9%]	[15.8%;100.0%]	[14.7%;94.7%]	[2.5%;100.0%]	[29.9%;92.5%]	[32.9%;81.6%]	[0.0%;97.5%]	[39.8%;100.0%]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C)								
n (%)	22 (56.4%)	0 (0.0%)	2 (40.0%)	1 (100.0%)	5 (55.6%)	9 (52.9%)	1 (100.0%)	4 (100.0%)
95% CI	[39.6%;72.2%]	[0.0%;84.2%]	[5.3%;85.3%]	[2.5%;100.0%]	[21.2%;86.3%]	[27.8%;77.0%]	[2.5%;100.0%]	[39.8%;100.0%]
Call your doctor: Nausea, vomiting (Q3D)								
n (%)	29 (74.4%)	0 (0.0%)	4 (80.0%)	1 (100.0%)	9 (100.0%)	12 (70.6%)	1 (100.0%)	2 (50.0%)
95% CI	[57.9%;87.0%]	[0.0%;84.2%]	[28.4%;99.5%]	[2.5%;100.0%]	[66.4%;100.0%]	[44.0%;89.7%]	[2.5%;100.0%]	[6.8%;93.2%]
Call your doctor: Difficulties with breathing, cough, fever (Q3E)								
n (%)	33 (84.6%)	2 (100.0%)	4 (80.0%)	1 (100.0%)	8 (88.9%)	13 (76.5%)	1 (100.0%)	4 (100.0%)
95% CI	[69.5%;94.1%]	[15.8%;100.0%]	[28.4%;99.5%]	[2.5%;100.0%]	[51.8%;99.7%]	[50.1%;93.2%]	[2.5%;100.0%]	[39.8%;100.0%]
Call your doctor: Itching, or bruised more easily than usual (Q3F)								
n (%)	21 (53.8%)	2 (100.0%)	1 (20.0%)	1 (100.0%)	6 (66.7%)	8 (47.1%)	1 (100.0%)	2 (50.0%)
95% CI	[37.2%;69.9%]	[15.8%;100.0%]	[0.5%;71.6%]	[2.5%;100.0%]	[29.9%;92.5%]	[23.0%;72.2%]	[2.5%;100.0%]	[6.8%;93.2%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 5: Effectiveness of the XALKORI Patient Information Brochure (PIB) Overall and by Country - Completer Analysis Set (page 1 of 3)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Awareness of the XALKORI PIB and the patient ID card included in the PIB								
Awareness of the XALKORI PIB (Q4)								
n (%)	18 (52.9%)	2 (100.0%)	1 (20.0%)	0 (0.0%)	4 (57.1%)	9 (64.3%)	0 (0.0%)	2 (50.0%)
95% CI	[35.1%;70.2%]	[15.8%;100.0%]	[0.5%;71.6%]	[0.0%;97.5%]	[18.4%;90.1%]	[35.1%;87.2%]	[0.0%;97.5%]	[6.8%;93.2%]
Receipt of the XALKORI PIB (Q5)								
n (%)	26 (76.5%)	2 (100.0%)	2 (40.0%)	0 (0.0%)	6 (85.7%)	13 (92.9%)	0 (0.0%)	3 (75.0%)
95% CI	[58.8%;89.3%]	[15.8%;100.0%]	[5.3%;85.3%]	[0.0%;97.5%]	[42.1%;99.6%]	[66.1%;99.8%]	[0.0%;97.5%]	[19.4%;99.4%]
Awareness of the patient ID card (Q13)[a]								
n (%)	12 (46.2%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	5 (83.3%)	3 (23.1%)	0 (0.0%)	1 (33.3%)
95% CI	[26.6%;66.6%]	[1.3%;98.7%]	[15.8%;100.0%]		[35.9%;99.6%]	[5.0%;53.8%]		[0.8%;90.6%]
Utilisation of the PIB								
Utilisation of the XALKORI PIB (Q7)[a]								
n (%)	25 (96.2%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	6 (100.0%)	13 (100.0%)	0 (0.0%)	3 (100.0%)
95% CI	[80.4%;99.9%]	[1.3%;98.7%]	[15.8%;100.0%]		[54.1%;100.0%]	[75.3%;100.0%]		[29.2%;100.0%]
Utilisation of the XALKORI patient ID card (Q14)[b]								
n (%)	2 (16.7%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)
95% CI	[2.1%;48.4%]	[2.5%;100.0%]	[0.0%;84.2%]		[0.0%;52.2%]	[0.8%;90.6%]		[0.0%;97.5%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 5: Effectiveness of the XALKORI Patient Information Brochure (PIB) Overall and by Country - Completer Analysis Set (page 2 of 3)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Knowledge/comprehension of the risks[c]								
Side effect: Breathing problems (Q1A)								
n (%)	12 (35.3%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	3 (42.9%)	3 (21.4%)	0 (0.0%)	3 (75.0%)
95% CI	[19.7%;53.5%]	[1.3%;98.7%]	[0.5%;71.6%]	[2.5%;100.0%]	[9.9%;81.6%]	[4.7%;50.8%]	[0.0%;97.5%]	[19.4%;99.4%]
Side effect: Abnormalities in liver blood tests (Q1B)								
n (%)	22 (64.7%)	1 (50.0%)	3 (60.0%)	0 (0.0%)	6 (85.7%)	8 (57.1%)	0 (0.0%)	4 (100.0%)
95% CI	[46.5%;80.3%]	[1.3%;98.7%]	[14.7%;94.7%]	[0.0%;97.5%]	[42.1%;99.6%]	[28.9%;82.3%]	[0.0%;97.5%]	[39.8%;100.0%]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)								
n (%)	23 (67.6%)	1 (50.0%)	2 (40.0%)	1 (100.0%)	6 (85.7%)	9 (64.3%)	0 (0.0%)	4 (100.0%)
95% CI	[49.5%;82.6%]	[1.3%;98.7%]	[5.3%;85.3%]	[2.5%;100.0%]	[42.1%;99.6%]	[35.1%;87.2%]	[0.0%;97.5%]	[39.8%;100.0%]
Side effect: Chest discomfort or irregular heartbeat (Q1F)								
n (%)	17 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (71.4%)	9 (64.3%)	0 (0.0%)	3 (75.0%)
95% CI	[32.4%;67.6%]	[0.0%;84.2%]	[0.0%;52.2%]	[0.0%;97.5%]	[29.0%;96.3%]	[35.1%;87.2%]	[0.0%;97.5%]	[19.4%;99.4%]
Side effect: Changes to vision (Q1G)								
n (%)	29 (85.3%)	1 (50.0%)	3 (60.0%)	1 (100.0%)	7 (100.0%)	13 (92.9%)	0 (0.0%)	4 (100.0%)
95% CI	[68.9%;95.0%]	[1.3%;98.7%]	[14.7%;94.7%]	[2.5%;100.0%]	[59.0%;100.0%]	[66.1%;99.8%]	[0.0%;97.5%]	[39.8%;100.0%]
Side effect: Slow in heart rate (Q1H)								
n (%)	13 (38.2%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	4 (57.1%)	5 (35.7%)	0 (0.0%)	2 (50.0%)
95% CI	[22.2%;56.4%]	[1.3%;98.7%]	[0.0%;52.2%]	[2.5%;100.0%]	[18.4%;90.1%]	[12.8%;64.9%]	[0.0%;97.5%]	[6.8%;93.2%]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A)								
n (%)	22 (64.7%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	6 (85.7%)	10 (71.4%)	0 (0.0%)	3 (75.0%)
95% CI	[46.5%;80.3%]	[1.3%;98.7%]	[0.5%;71.6%]	[2.5%;100.0%]	[42.1%;99.6%]	[41.9%;91.6%]	[0.0%;97.5%]	[19.4%;99.4%]
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B)								
n (%)	26 (76.5%)	1 (50.0%)	5 (100.0%)	1 (100.0%)	4 (57.1%)	10 (71.4%)	1 (100.0%)	4 (100.0%)
95% CI	[58.8%;89.3%]	[1.3%;98.7%]	[47.8%;100.0%]	[2.5%;100.0%]	[18.4%;90.1%]	[41.9%;91.6%]	[2.5%;100.0%]	[39.8%;100.0%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 5: Effectiveness of the XALKORI Patient Information Brochure (PIB) Overall and by Country - Completer Analysis Set (page 3 of 3)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)								
n (%)	18 (52.9%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	5 (71.4%)	7 (50.0%)	0 (0.0%)	4 (100.0%)
95% CI	[35.1%;70.2%]	[1.3%;98.7%]	[0.5%;71.6%]	[0.0%;97.5%]	[29.0%;96.3%]	[23.0%;77.0%]	[0.0%;97.5%]	[39.8%;100.0%]
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A)								
n (%)	28 (82.4%)	2 (100.0%)	2 (40.0%)	1 (100.0%)	7 (100.0%)	12 (85.7%)	0 (0.0%)	4 (100.0%)
95% CI	[65.5%;93.2%]	[15.8%;100.0%]	[5.3%;85.3%]	[2.5%;100.0%]	[59.0%;100.0%]	[57.2%;98.2%]	[0.0%;97.5%]	[39.8%;100.0%]
Call your doctor: Skin and whites of your eyes turn yellow (Q3B)								
n (%)	24 (70.6%)	2 (100.0%)	3 (60.0%)	1 (100.0%)	6 (85.7%)	8 (57.1%)	0 (0.0%)	4 (100.0%)
95% CI	[52.5%;84.9%]	[15.8%;100.0%]	[14.7%;94.7%]	[2.5%;100.0%]	[42.1%;99.6%]	[28.9%;82.3%]	[0.0%;97.5%]	[39.8%;100.0%]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C)								
n (%)	19 (55.9%)	0 (0.0%)	2 (40.0%)	1 (100.0%)	5 (71.4%)	6 (42.9%)	1 (100.0%)	4 (100.0%)
95% CI	[37.9%;72.8%]	[0.0%;84.2%]	[5.3%;85.3%]	[2.5%;100.0%]	[29.0%;96.3%]	[17.7%;71.1%]	[2.5%;100.0%]	[39.8%;100.0%]
Call your doctor: Nausea, vomiting (Q3D)								
n (%)	24 (70.6%)	0 (0.0%)	4 (80.0%)	1 (100.0%)	7 (100.0%)	9 (64.3%)	1 (100.0%)	2 (50.0%)
95% CI	[52.5%;84.9%]	[0.0%;84.2%]	[28.4%;99.5%]	[2.5%;100.0%]	[59.0%;100.0%]	[35.1%;87.2%]	[2.5%;100.0%]	[6.8%;93.2%]
Call your doctor: Difficulties with breathing, cough, fever (Q3E)								
n (%)	29 (85.3%)	2 (100.0%)	4 (80.0%)	1 (100.0%)	7 (100.0%)	10 (71.4%)	1 (100.0%)	4 (100.0%)
95% CI	[68.9%;95.0%]	[15.8%;100.0%]	[28.4%;99.5%]	[2.5%;100.0%]	[59.0%;100.0%]	[41.9%;91.6%]	[2.5%;100.0%]	[39.8%;100.0%]
Call your doctor: Itching, or bruised more easily than usual (Q3F)								
n (%)	18 (52.9%)	2 (100.0%)	1 (20.0%)	1 (100.0%)	5 (71.4%)	6 (42.9%)	1 (100.0%)	2 (50.0%)
95% CI	[35.1%;70.2%]	[15.8%;100.0%]	[0.5%;71.6%]	[2.5%;100.0%]	[29.0%;96.3%]	[17.7%;71.1%]	[2.5%;100.0%]	[6.8%;93.2%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 6: Effectiveness of the XALKORI Patient Information Brochure (PIB), by PIB Reading Status – Full Analysis Set (page 1 of 2)

	Read[a] N=28	Not Read or Not received[a] N=11	Overall N=39
Knowledge/comprehension of the risks[b]			
Side effect: Breathing problems (Q1A)			
n (%)	11 (39.3%)	3 (27.3%)	14 (35.9%)
95% CI	[21.5%;59.4%]	[6.0%;61.0%]	[21.2%;52.8%]
Side effect: Abnormalities in liver blood tests (Q1B)			
n (%)	18 (64.3%)	6 (54.5%)	24 (61.5%)
95% CI	[44.1%;81.4%]	[23.4%;83.3%]	[44.6%;76.6%]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)			
n (%)	22 (78.6%)	5 (45.5%)	27 (69.2%)
95% CI	[59.0%;91.7%]	[16.7%;76.6%]	[52.4%;83.0%]
Side effect: Chest discomfort or irregular heartbeat (Q1F)			
n (%)	16 (57.1%)	3 (27.3%)	19 (48.7%)
95% CI	[37.2%;75.5%]	[6.0%;61.0%]	[32.4%;65.2%]
Side effect: Changes to vision (Q1G)			
n (%)	27 (96.4%)	6 (54.5%)	33 (84.6%)
95% CI	[81.7%;99.9%]	[23.4%;83.3%]	[69.5%;94.1%]
Side effect: Slow in heart rate (Q1H)			
n (%)	12 (42.9%)	3 (27.3%)	15 (38.5%)
95% CI	[24.5%;62.8%]	[6.0%;61.0%]	[23.4%;55.4%]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A)			
n (%)	21 (75.0%)	5 (45.5%)	26 (66.7%)
95% CI	[55.1%;89.3%]	[16.7%;76.6%]	[49.8%;80.9%]
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B)			
n (%)	19 (67.9%)	8 (72.7%)	27 (69.2%)
95% CI	[47.6%;84.1%]	[39.0%;94.0%]	[52.4%;83.0%]
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)			
n (%)	18 (64.3%)	4 (36.4%)	22 (56.4%)
95% CI	[44.1%;81.4%]	[10.9%;69.2%]	[39.6%;72.2%]
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A)			
n (%)	25 (89.3%)	8 (72.7%)	33 (84.6%)
95% CI	[71.8%;97.7%]	[39.0%;94.0%]	[69.5%;94.1%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods

[a] The variable 'PIB Reading Status' is defined as:
- 'Read' if Q5 (PIB received)='Yes' and Q7 (Amount of reading)='All of it' or 'Some of it';
- 'Not Read or Not received' otherwise.

[b] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 6: Effectiveness of the XALKORI Patient Information Brochure (PIB), by PIB Reading Status – Full Analysis Set (page 2 of 2)

	Read[a] N=28	Not Read or Not received[a] N=11	Overall N=39
Call your doctor: Skin and whites of your eyes turn yellow (Q3B)			
n (%)	20 (71.4%)	6 (54.5%)	26 (66.7%)
95% CI	[51.3%;86.8%]	[23.4%;83.3%]	[49.8%;80.9%]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C)			
n (%)	16 (57.1%)	6 (54.5%)	22 (56.4%)
95% CI	[37.2%;75.5%]	[23.4%;83.3%]	[39.6%;72.2%]
Call your doctor: Nausea, vomiting (Q3D)			
n (%)	20 (71.4%)	9 (81.8%)	29 (74.4%)
95% CI	[51.3%;86.8%]	[48.2%;97.7%]	[57.9%;87.0%]
Call your doctor: Difficulties with breathing, cough, fever (Q3E)			
n (%)	23 (82.1%)	10 (90.9%)	33 (84.6%)
95% CI	[63.1%;93.9%]	[58.7%;99.8%]	[69.5%;94.1%]
Call your doctor: Itching, or bruised more easily than usual (Q3F)			
n (%)	15 (53.6%)	6 (54.5%)	21 (53.8%)
95% CI	[33.9%;72.5%]	[23.4%;83.3%]	[37.2%;69.9%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods

[a] The variable 'PIB Reading Status' is defined as:
- 'Read' if Q5 (PIB received)='Yes' and Q7 (Amount of reading)='All of it' or 'Some of it';
- 'Not Read or Not received' otherwise.

[b] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 7: Effectiveness of the XALKORI Patient Information Brochure (PIB), by PIB Reading Status – Completer Analysis Set (page 1 of 2)

	Read[a] N=25	Not Read or Not received[a] N=9	Overall N=34
Knowledge/comprehension of the risks[b]			
Side effect: Breathing problems (Q1A)			
n (%)	10 (40.0%)	2 (22.2%)	12 (35.3%)
95% CI	[21.1%;61.3%]	[2.8%;60.0%]	[19.7%;53.5%]
Side effect: Abnormalities in liver blood tests (Q1B)			
n (%)	17 (68.0%)	5 (55.6%)	22 (64.7%)
95% CI	[46.5%;85.1%]	[21.2%;86.3%]	[46.5%;80.3%]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)			
n (%)	20 (80.0%)	3 (33.3%)	23 (67.6%)
95% CI	[59.3%;93.2%]	[7.5%;70.1%]	[49.5%;82.6%]
Side effect: Chest discomfort or irregular heartbeat (Q1F)			
n (%)	15 (60.0%)	2 (22.2%)	17 (50.0%)
95% CI	[38.7%;78.9%]	[2.8%;60.0%]	[32.4%;67.6%]
Side effect: Changes to vision (Q1G)			
n (%)	24 (96.0%)	5 (55.6%)	29 (85.3%)
95% CI	[79.6%;99.9%]	[21.2%;86.3%]	[68.9%;95.0%]
Side effect: Slow in heart rate (Q1H)			
n (%)	11 (44.0%)	2 (22.2%)	13 (38.2%)
95% CI	[24.4%;65.1%]	[2.8%;60.0%]	[22.2%;56.4%]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A)			
n (%)	18 (72.0%)	4 (44.4%)	22 (64.7%)
95% CI	[50.6%;87.9%]	[13.7%;78.8%]	[46.5%;80.3%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] The variable 'PIB Reading Status' is defined as:
- 'Read' if Q5 (PIB received)='Yes' and Q7 (Amount of reading)='All of it' or 'Some of it';
- 'Not Read or Not received' otherwise.
[b] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 7: Effectiveness of the XALKORI Patient Information Brochure (PIB), by PIB Reading Status – Completer Analysis Set (page 2 of 2)

	Read[a] N=25	Not Read or Not received[a] N=9	Overall N=34
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B)			
n (%)	18 (72.0%)	8 (88.9%)	26 (76.5%)
95% CI	[50.6%;87.9%]	[51.8%;99.7%]	[58.8%;89.3%]
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)			
n (%)	15 (60.0%)	3 (33.3%)	18 (52.9%)
95% CI	[38.7%;78.9%]	[7.5%;70.1%]	[35.1%;70.2%]
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A)			
n (%)	22 (88.0%)	6 (66.7%)	28 (82.4%)
95% CI	[68.8%;97.5%]	[29.9%;92.5%]	[65.5%;93.2%]
Call your doctor: Skin and whites of your eyes turn yellow (Q3B)			
n (%)	18 (72.0%)	6 (66.7%)	24 (70.6%)
95% CI	[50.6%;87.9%]	[29.9%;92.5%]	[52.5%;84.9%]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C)			
n (%)	14 (56.0%)	5 (55.6%)	19 (55.9%)
95% CI	[34.9%;75.6%]	[21.2%;86.3%]	[37.9%;72.8%]
Call your doctor: Nausea, vomiting (Q3D)			
n (%)	17 (68.0%)	7 (77.8%)	24 (70.6%)
95% CI	[46.5%;85.1%]	[40.0%;97.2%]	[52.5%;84.9%]
Call your doctor: Difficulties with breathing, cough, fever (Q3E)			
n (%)	21 (84.0%)	8 (88.9%)	29 (85.3%)
95% CI	[63.9%;95.5%]	[51.8%;99.7%]	[68.9%;95.0%]
Call your doctor: Itching, or bruised more easily than usual (Q3F)			
n (%)	14 (56.0%)	4 (44.4%)	18 (52.9%)
95% CI	[34.9%;75.6%]	[13.7%;78.8%]	[35.1%;70.2%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] The variable 'PIB Reading Status' is defined as:
- 'Read' if Q5 (PIB received)='Yes' and Q7 (Amount of reading)='All of it' or 'Some of it';
- 'Not Read or Not received' otherwise.
[b] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 8: Knowledge of Side Effects, Precaution for Use, and When to Call a Doctor, by Patient Information Brochure (PIB) Reading Status - Full Analysis Set

	Read[a] N=28	Not Read or Not received[a] N=11	Overall N=39
Number of correct answers regarding side effects associated with XALKORI treatment (/ 9 questions: Q1A-1I)			
0	0 (0.0%)	1 (9.1%)	1 (2.6%)
1-4	9 (32.1%)	5 (45.5%)	14 (35.9%)
5-8	16 (57.1%)	3 (27.3%)	19 (48.7%)
9	1 (3.6%)	0 (0.0%)	1 (2.6%)
MD	2 (7.1%)	2 (18.2%)	4 (10.3%)
Number of correct answers regarding precaution for use of XALKORI (/ 3 questions: Q2A-2C)			
0	2 (7.1%)	1 (9.1%)	3 (7.7%)
1-2	16 (57.1%)	8 (72.7%)	24 (61.5%)
3	10 (35.7%)	2 (18.2%)	12 (30.8%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of correct answers regarding reasons for calling a doctor (/ 7 questions: Q3A-3G)			
0	0 (0.0%)	0 (0.0%)	0 (0.0%)
1-3	7 (25.0%)	3 (27.3%)	10 (25.6%)
4-6	20 (71.4%)	8 (72.7%)	28 (71.8%)
7	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	1 (3.6%)	0 (0.0%)	1 (2.6%)
Number of correct answers regarding side effects associated with XALKORI treatment, precaution for use of XALKORI, and reasons for calling a doctor (/ 19 questions)			
0	0 (0.0%)	0 (0.0%)	0 (0.0%)
1-6	4 (14.3%)	1 (9.1%)	5 (12.8%)
7-12	10 (35.7%)	7 (63.6%)	17 (43.6%)
13-18	11 (39.3%)	1 (9.1%)	12 (30.8%)
19	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	3 (10.7%)	2 (18.2%)	5 (12.8%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
[a] The variable 'PIB Reading Status' is defined as:
- 'Read' if Q5 (PIB received)='Yes' and Q7 (Amount of reading)='All of it' or 'Some of it';
- 'Not Read or Not received' otherwise.
MD=Missing data

Table 9: Knowledge of Side Effects, Precaution for Use, and When to Call a Doctor, by Patient Information Brochure (PIB) Reading Status - Completer Analysis Set

	Read[a] N=25	Not Read or Not received[a] N=9	Overall N=34
Number of correct answers regarding side effects associated with XALKORI treatment (/ 9 questions: Q1A-1I)			
0	0 (0.0%)	1 (11.1%)	1 (2.9%)
1-4	9 (36.0%)	5 (55.6%)	14 (41.2%)
5-8	15 (60.0%)	3 (33.3%)	18 (52.9%)
9	1 (4.0%)	0 (0.0%)	1 (2.9%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of correct answers regarding precaution for use of XALKORI (/ 3 questions: Q2A-2C)			
0	2 (8.0%)	1 (11.1%)	3 (8.8%)
1-2	14 (56.0%)	6 (66.7%)	20 (58.8%)
3	9 (36.0%)	2 (22.2%)	11 (32.4%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of correct answers regarding reasons for calling a doctor (/ 7 questions: Q3A-3G)			
0	0 (0.0%)	0 (0.0%)	0 (0.0%)
1-3	7 (28.0%)	3 (33.3%)	10 (29.4%)
4-6	18 (72.0%)	6 (66.7%)	24 (70.6%)
7	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)
Number of correct answers regarding side effects associated with XALKORI treatment, precaution for use of XALKORI, and reasons for calling a doctor (/ 19 questions)			
0	0 (0.0%)	0 (0.0%)	0 (0.0%)
1-6	4 (16.0%)	1 (11.1%)	5 (14.7%)
7-12	10 (40.0%)	7 (77.8%)	17 (50.0%)
13-18	11 (44.0%)	1 (11.1%)	12 (35.3%)
19	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)

[a] The variable 'PIB Reading Status' is defined as:
- 'Read' if Q5 (PIB received)='Yes' and Q7 (Amount of reading)='All of it' or 'Some of it';
- 'Not Read or Not received' otherwise.

MD=Missing data

Table 10: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Age Group – Full Analysis Set (page 1 of 3)

	18 to 64 Years N=30	65 Years and Older N=9	Overall N=39
Awareness of the XALKORI PIB and the patient ID card included in the PIB			
Awareness of the XALKORI PIB (Q4)			
n (%)	14 (46.7%)	5 (55.6%)	19 (48.7%)
95% CI	[28.3%;65.7%]	[21.2%;86.3%]	[32.4%;65.2%]
Receipt of the XALKORI PIB (Q5)			
n (%)	23 (76.7%)	7 (77.8%)	30 (76.9%)
95% CI	[57.7%;90.1%]	[40.0%;97.2%]	[60.7%;88.9%]
Awareness of the patient ID card (Q13)[a]			
n (%)	9 (39.1%)	5 (71.4%)	14 (46.7%)
95% CI	[19.7%;61.5%]	[29.0%;96.3%]	[28.3%;65.7%]
Utilisation of the PIB			
Utilisation of the XALKORI PIB (Q7)[a]			
n (%)	21 (91.3%)	7 (100.0%)	28 (93.3%)
95% CI	[72.0%;98.9%]	[59.0%;100.0%]	[77.9%;99.2%]
Utilisation of the XALKORI patient ID card (Q14)[b]			
n (%)	3 (33.3%)	0 (0.0%)	3 (21.4%)
95% CI	[7.5%;70.1%]	[0.0%;52.2%]	[4.7%;50.8%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 10: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Age Group – Full Analysis Set (page 2 of 3)

	18 to 64 Years N=30	65 Years and Older N=9	Overall N=39
Knowledge/comprehension of the risks[c]			
Side effect: Breathing problems (Q1A)			
n (%)	11 (36.7%)	3 (33.3%)	14 (35.9%)
95% CI	[19.9%;56.1%]	[7.5%;70.1%]	[21.2%;52.8%]
Side effect: Abnormalities in liver blood tests (Q1B)			
n (%)	18 (60.0%)	6 (66.7%)	24 (61.5%)
95% CI	[40.6%;77.3%]	[29.9%;92.5%]	[44.6%;76.6%]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)			
n (%)	20 (66.7%)	7 (77.8%)	27 (69.2%)
95% CI	[47.2%;82.7%]	[40.0%;97.2%]	[52.4%;83.0%]
Side effect: Chest discomfort or irregular heartbeat (Q1F)			
n (%)	13 (43.3%)	6 (66.7%)	19 (48.7%)
95% CI	[25.5%;62.6%]	[29.9%;92.5%]	[32.4%;65.2%]
Side effect: Changes to vision (Q1G)			
n (%)	25 (83.3%)	8 (88.9%)	33 (84.6%)
95% CI	[65.3%;94.4%]	[51.8%;99.7%]	[69.5%;94.1%]
Side effect: Slow in heart rate (Q1H)			
n (%)	10 (33.3%)	5 (55.6%)	15 (38.5%)
95% CI	[17.3%;52.8%]	[21.2%;86.3%]	[23.4%;55.4%]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A)			
n (%)	20 (66.7%)	6 (66.7%)	26 (66.7%)
95% CI	[47.2%;82.7%]	[29.9%;92.5%]	[49.8%;80.9%]
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B)			
n (%)	20 (66.7%)	7 (77.8%)	27 (69.2%)
95% CI	[47.2%;82.7%]	[40.0%;97.2%]	[52.4%;83.0%]
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)			
n (%)	20 (66.7%)	2 (22.2%)	22 (56.4%)
95% CI	[47.2%;82.7%]	[2.8%;60.0%]	[39.6%;72.2%]
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A)			
n (%)	26 (86.7%)	7 (77.8%)	33 (84.6%)
95% CI	[69.3%;96.2%]	[40.0%;97.2%]	[69.5%;94.1%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 10: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Age Group – Full Analysis Set (page 3 of 3)

	18 to 64 Years N=30	65 Years and Older N=9	Overall N=39
Call your doctor: Skin and whites of your eyes turn yellow (Q3B)			
n (%)	21 (70.0%)	5 (55.6%)	26 (66.7%)
95% CI	[50.6%;85.3%]	[21.2%;86.3%]	[49.8%;80.9%]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C)			
n (%)	16 (53.3%)	6 (66.7%)	22 (56.4%)
95% CI	[34.3%;71.7%]	[29.9%;92.5%]	[39.6%;72.2%]
Call your doctor: Nausea, vomiting (Q3D)			
n (%)	22 (73.3%)	7 (77.8%)	29 (74.4%)
95% CI	[54.1%;87.7%]	[40.0%;97.2%]	[57.9%;87.0%]
Call your doctor: Difficulties with breathing, cough, fever (Q3E)			
n (%)	24 (80.0%)	9 (100.0%)	33 (84.6%)
95% CI	[61.4%;92.3%]	[66.4%;100.0%]	[69.5%;94.1%]
Call your doctor: Itching, or bruised more easily than usual (Q3F)			
n (%)	16 (53.3%)	5 (55.6%)	21 (53.8%)
95% CI	[34.3%;71.7%]	[21.2%;86.3%]	[37.2%;69.9%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 11: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Age Group – Completer Analysis Set (page 1 of 3)

	18 to 64 Years N=25	65 Years and Older N=9	Overall N=34
Awareness of the XALKORI PIB and the patient ID card included in the PIB			
Awareness of the XALKORI PIB (Q4)			
n (%)	13 (52.0%)	5 (55.6%)	18 (52.9%)
95% CI	[31.3%;72.2%]	[21.2%;86.3%]	[35.1%;70.2%]
Receipt of the XALKORI PIB (Q5)			
n (%)	19 (76.0%)	7 (77.8%)	26 (76.5%)
95% CI	[54.9%;90.6%]	[40.0%;97.2%]	[58.8%;89.3%]
Awareness of the patient ID card (Q13)[a]			
n (%)	7 (36.8%)	5 (71.4%)	12 (46.2%)
95% CI	[16.3%;61.6%]	[29.0%;96.3%]	[26.6%;66.6%]
Utilisation of the PIB			
Utilisation of the XALKORI PIB (Q7)[a]			
n (%)	18 (94.7%)	7 (100.0%)	25 (96.2%)
95% CI	[74.0%;99.9%]	[59.0%;100.0%]	[80.4%;99.9%]
Utilisation of the XALKORI patient ID card (Q14)[b]			
n (%)	2 (28.6%)	0 (0.0%)	2 (16.7%)
95% CI	[3.7%;71.0%]	[0.0%;52.2%]	[2.1%;48.4%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 11: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Age Group – Completer Analysis Set (page 2 of 3)

	18 to 64 Years N=25	65 Years and Older N=9	Overall N=34
Knowledge/comprehension of the risks[c]			
Side effect: Breathing problems (Q1A)			
n (%)	9 (36.0%)	3 (33.3%)	12 (35.3%)
95% CI	[18.0%;57.5%]	[7.5%;70.1%]	[19.7%;53.5%]
Side effect: Abnormalities in liver blood tests (Q1B)			
n (%)	16 (64.0%)	6 (66.7%)	22 (64.7%)
95% CI	[42.5%;82.0%]	[29.9%;92.5%]	[46.5%;80.3%]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)			
n (%)	16 (64.0%)	7 (77.8%)	23 (67.6%)
95% CI	[42.5%;82.0%]	[40.0%;97.2%]	[49.5%;82.6%]
Side effect: Chest discomfort or irregular heartbeat (Q1F)			
n (%)	11 (44.0%)	6 (66.7%)	17 (50.0%)
95% CI	[24.4%;65.1%]	[29.9%;92.5%]	[32.4%;67.6%]
Side effect: Changes to vision (Q1G)			
n (%)	21 (84.0%)	8 (88.9%)	29 (85.3%)
95% CI	[63.9%;95.5%]	[51.8%;99.7%]	[68.9%;95.0%]
Side effect: Slow in heart rate (Q1H)			
n (%)	8 (32.0%)	5 (55.6%)	13 (38.2%)
95% CI	[14.9%;53.5%]	[21.2%;86.3%]	[22.2%;56.4%]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A)			
n (%)	16 (64.0%)	6 (66.7%)	22 (64.7%)
95% CI	[42.5%;82.0%]	[29.9%;92.5%]	[46.5%;80.3%]
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B)			
n (%)	19 (76.0%)	7 (77.8%)	26 (76.5%)
95% CI	[54.9%;90.6%]	[40.0%;97.2%]	[58.8%;89.3%]
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)			
n (%)	16 (64.0%)	2 (22.2%)	18 (52.9%)
95% CI	[42.5%;82.0%]	[2.8%;60.0%]	[35.1%;70.2%]
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A)			
n (%)	21 (84.0%)	7 (77.8%)	28 (82.4%)
95% CI	[63.9%;95.5%]	[40.0%;97.2%]	[65.5%;93.2%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 11: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Age Group – Completer Analysis Set (page 3 of 3)

	18 to 64 Years N=25	65 Years and Older N=9	Overall N=34
Call your doctor: Skin and whites of your eyes turn yellow (Q3B)			
n (%)	19 (76.0%)	5 (55.6%)	24 (70.6%)
95% CI	[54.9%;90.6%]	[21.2%;86.3%]	[52.5%;84.9%]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C)			
n (%)	13 (52.0%)	6 (66.7%)	19 (55.9%)
95% CI	[31.3%;72.2%]	[29.9%;92.5%]	[37.9%;72.8%]
Call your doctor: Nausea, vomiting (Q3D)			
n (%)	17 (68.0%)	7 (77.8%)	24 (70.6%)
95% CI	[46.5%;85.1%]	[40.0%;97.2%]	[52.5%;84.9%]
Call your doctor: Difficulties with breathing, cough, fever (Q3E)			
n (%)	20 (80.0%)	9 (100.0%)	29 (85.3%)
95% CI	[59.3%;93.2%]	[66.4%;100.0%]	[68.9%;95.0%]
Call your doctor: Itching, or bruised more easily than usual (Q3F)			
n (%)	13 (52.0%)	5 (55.6%)	18 (52.9%)
95% CI	[31.3%;72.2%]	[21.2%;86.3%]	[35.1%;70.2%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.

Table 12: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Education Level – Full Analysis Set (page 1 of 3)

	Primary School N=7	Secondary School N=11	University/Higher Education N=13	Prefer not to Answer N=1	Overall* N=32
Awareness of the XALKORI PIB and the patient ID card included in the PIB					
Awareness of the XALKORI PIB (Q4)					
n (%)	4 (57.1%)	4 (36.4%)	5 (38.5%)	1 (100.0%)	14 (43.8%)
95% CI	[18.4%;90.1%]	[10.9%;69.2%]	[13.9%;68.4%]	[2.5%;100.0%]	[26.4%;62.3%]
Receipt of the XALKORI PIB (Q5)					
n (%)	7 (100.0%)	9 (81.8%)	8 (61.5%)	1 (100.0%)	25 (78.1%)
95% CI	[59.0%;100.0%]	[48.2%;97.7%]	[31.6%;86.1%]	[2.5%;100.0%]	[60.0%;90.7%]
Awareness of the patient ID card (Q13)[a]					
n (%)	4 (57.1%)	4 (44.4%)	1 (12.5%)	1 (100.0%)	10 (40.0%)
95% CI	[18.4%;90.1%]	[13.7%;78.8%]	[0.3%;52.7%]	[2.5%;100.0%]	[21.1%;61.3%]
Utilisation of the PIB					
Utilisation of the XALKORI PIB (Q7)[a]					
n (%)	6 (85.7%)	9 (100.0%)	7 (87.5%)	1 (100.0%)	23 (92.0%)
95% CI	[42.1%;99.6%]	[66.4%;100.0%]	[47.3%;99.7%]	[2.5%;100.0%]	[74.0%;99.0%]
Utilisation of the XALKORI patient ID card (Q14)[b]					
n (%)	2 (50.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	3 (30.0%)
95% CI	[6.8%;93.2%]	[0.0%;60.2%]	[2.5%;100.0%]	[0.0%;97.5%]	[6.7%;65.2%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.
* The variable 'Education Level' is missing for 7 patients

Table 12: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Education Level – Full Analysis Set (page 2 of 3)

	Primary School N=7	Secondary School N=11	University/Higher Education N=13	Prefer not to Answer N=1	Overall* N=32
Knowledge/comprehension of the risks[c]					
Side effect: Breathing problems (Q1A)					
n (%)	3 (42.9%)	2 (18.2%)	5 (38.5%)	1 (100.0%)	11 (34.4%)
95% CI	[9.9%;81.6%]	[2.3%;51.8%]	[13.9%;68.4%]	[2.5%;100.0%]	[18.6%;53.2%]
Side effect: Abnormalities in liver blood tests (Q1B)					
n (%)	6 (85.7%)	3 (27.3%)	8 (61.5%)	1 (100.0%)	18 (56.3%)
95% CI	[42.1%;99.6%]	[6.0%;61.0%]	[31.6%;86.1%]	[2.5%;100.0%]	[37.7%;73.6%]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)					
n (%)	6 (85.7%)	5 (45.5%)	9 (69.2%)	1 (100.0%)	21 (65.6%)
95% CI	[42.1%;99.6%]	[16.7%;76.6%]	[38.6%;90.9%]	[2.5%;100.0%]	[46.8%;81.4%]
Side effect: Chest discomfort or irregular heartbeat (Q1F)					
n (%)	5 (71.4%)	4 (36.4%)	4 (30.8%)	1 (100.0%)	14 (43.8%)
95% CI	[29.0%;96.3%]	[10.9%;69.2%]	[9.1%;61.4%]	[2.5%;100.0%]	[26.4%;62.3%]
Side effect: Changes to vision (Q1G)					
n (%)	7 (100.0%)	8 (72.7%)	11 (84.6%)	1 (100.0%)	27 (84.4%)
95% CI	[59.0%;100.0%]	[39.0%;94.0%]	[54.6%;98.1%]	[2.5%;100.0%]	[67.2%;94.7%]
Side effect: Slow in heart rate (Q1H)					
n (%)	5 (71.4%)	1 (9.1%)	5 (38.5%)	1 (100.0%)	12 (37.5%)
95% CI	[29.0%;96.3%]	[0.2%;41.3%]	[13.9%;68.4%]	[2.5%;100.0%]	[21.1%;56.3%]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A)					
n (%)	7 (100.0%)	8 (72.7%)	5 (38.5%)	1 (100.0%)	21 (65.6%)
95% CI	[59.0%;100.0%]	[39.0%;94.0%]	[13.9%;68.4%]	[2.5%;100.0%]	[46.8%;81.4%]
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B)					
n (%)	5 (71.4%)	6 (54.5%)	11 (84.6%)	1 (100.0%)	23 (71.9%)
95% CI	[29.0%;96.3%]	[23.4%;83.3%]	[54.6%;98.1%]	[2.5%;100.0%]	[53.3%;86.3%]
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)					
n (%)	3 (42.9%)	5 (45.5%)	8 (61.5%)	1 (100.0%)	17 (53.1%)
95% CI	[9.9%;81.6%]	[16.7%;76.6%]	[31.6%;86.1%]	[2.5%;100.0%]	[34.7%;70.9%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.
* The variable 'Education Level' is missing for 7 patients

Table 12: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Education Level – Full Analysis Set (page 3 of 3)

	Primary School N=7	Secondary School N=11	University/Higher Education N=13	Prefer not to Answer N=1	Overall* N=32
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A)					
n (%)	7 (100.0%)	8 (72.7%)	10 (76.9%)	1 (100.0%)	26 (81.3%)
95% CI	[59.0%;100.0%]	[39.0%;94.0%]	[46.2%;95.0%]	[2.5%;100.0%]	[63.6%;92.8%]
Call your doctor: Skin and whites of your eyes turn yellow (Q3B)					
n (%)	5 (71.4%)	7 (63.6%)	8 (61.5%)	1 (100.0%)	21 (65.6%)
95% CI	[29.0%;96.3%]	[30.8%;89.1%]	[31.6%;86.1%]	[2.5%;100.0%]	[46.8%;81.4%]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C)					
n (%)	5 (71.4%)	4 (36.4%)	8 (61.5%)	1 (100.0%)	18 (56.3%)
95% CI	[29.0%;96.3%]	[10.9%;69.2%]	[31.6%;86.1%]	[2.5%;100.0%]	[37.7%;73.6%]
Call your doctor: Nausea, vomiting (Q3D)					
n (%)	5 (71.4%)	8 (72.7%)	8 (61.5%)	1 (100.0%)	22 (68.8%)
95% CI	[29.0%;96.3%]	[39.0%;94.0%]	[31.6%;86.1%]	[2.5%;100.0%]	[50.0%;83.9%]
Call your doctor: Difficulties with breathing, cough, fever (Q3E)					
n (%)	7 (100.0%)	8 (72.7%)	10 (76.9%)	1 (100.0%)	26 (81.3%)
95% CI	[59.0%;100.0%]	[39.0%;94.0%]	[46.2%;95.0%]	[2.5%;100.0%]	[63.6%;92.8%]
Call your doctor: Itching, or bruised more easily than usual (Q3F)					
n (%)	4 (57.1%)	5 (45.5%)	6 (46.2%)	1 (100.0%)	16 (50.0%)
95% CI	[18.4%;90.1%]	[16.7%;76.6%]	[19.2%;74.9%]	[2.5%;100.0%]	[31.9%;68.1%]

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.
* The variable 'Education Level' is missing for 7 patients

Table 13: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Education Level – Completer Analysis Set (page 1 of 4)

	Primary School N=5	Secondary School N=9	University/Higher Education N=13	Prefer not to Answer N=1	Overall* N=28
Awareness of the XALKORI PIB and the patient ID card included in the PIB					
Awareness of the XALKORI PIB (Q4)					
n (%)	4 (80.0%)	4 (44.4%)	5 (38.5%)	1 (100.0%)	14 (50.0%)
95% CI	[28.4%;99.5%]	[13.7%;78.8%]	[13.9%;68.4%]	[2.5%;100.0%]	[30.6%;69.4%]
Receipt of the XALKORI PIB (Q5)					
n (%)	5 (100.0%)	7 (77.8%)	8 (61.5%)	1 (100.0%)	21 (75.0%)
95% CI	[47.8%;100.0%]	[40.0%;97.2%]	[31.6%;86.1%]	[2.5%;100.0%]	[55.1%;89.3%]
Awareness of the patient ID card (Q13)[a]					
n (%)	2 (40.0%)	4 (57.1%)	1 (12.5%)	1 (100.0%)	8 (38.1%)
95% CI	[5.3%;85.3%]	[18.4%;90.1%]	[0.3%;52.7%]	[2.5%;100.0%]	[18.1%;61.6%]
Utilisation of the PIB					
Utilisation of the XALKORI PIB (Q7)[a]					
n (%)	5 (100.0%)	7 (100.0%)	7 (87.5%)	1 (100.0%)	20 (95.2%)
95% CI	[47.8%;100.0%]	[59.0%;100.0%]	[47.3%;99.7%]	[2.5%;100.0%]	[76.2%;99.9%]
Utilisation of the XALKORI patient ID card (Q14)[b]					
n (%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	2 (25.0%)
95% CI	[1.3%;98.7%]	[0.0%;60.2%]	[2.5%;100.0%]	[0.0%;97.5%]	[3.2%;65.1%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.
* The variable 'Education Level' is missing for 6 patients

Table 13: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Education Level – Completer Analysis Set (page 2 of 4)

	Primary School N=5	Secondary School N=9	University/Higher Education N=13	Prefer not to Answer N=1	Overall* N=28
Knowledge/comprehension of the risks[c]					
Side effect: Breathing problems (Q1A)					
n (%)	1 (20.0%)	2 (22.2%)	5 (38.5%)	1 (100.0%)	9 (32.1%)
95% CI	[0.5%;71.6%]	[2.8%;60.0%]	[13.9%;68.4%]	[2.5%;100.0%]	[15.9%;52.4%]
Side effect: Abnormalities in liver blood tests (Q1B)					
n (%)	5 (100.0%)	3 (33.3%)	8 (61.5%)	1 (100.0%)	17 (60.7%)
95% CI	[47.8%;100.0%]	[7.5%;70.1%]	[31.6%;86.1%]	[2.5%;100.0%]	[40.6%;78.5%]
Side effect: Dizziness, light-headedness, fainting, tiredness (Q1D)					
n (%)	4 (80.0%)	4 (44.4%)	9 (69.2%)	1 (100.0%)	18 (64.3%)
95% CI	[28.4%;99.5%]	[13.7%;78.8%]	[38.6%;90.9%]	[2.5%;100.0%]	[44.1%;81.4%]
Side effect: Chest discomfort or irregular heartbeat (Q1F)					
n (%)	4 (80.0%)	4 (44.4%)	4 (30.8%)	1 (100.0%)	13 (46.4%)
95% CI	[28.4%;99.5%]	[13.7%;78.8%]	[9.1%;61.4%]	[2.5%;100.0%]	[27.5%;66.1%]
Side effect: Changes to vision (Q1G)					
n (%)	5 (100.0%)	6 (66.7%)	11 (84.6%)	1 (100.0%)	23 (82.1%)
95% CI	[47.8%;100.0%]	[29.9%;92.5%]	[54.6%;98.1%]	[2.5%;100.0%]	[63.1%;93.9%]
Side effect: Slow in heart rate (Q1H)					
n (%)	3 (60.0%)	1 (11.1%)	5 (38.5%)	1 (100.0%)	10 (35.7%)
95% CI	[14.7%;94.7%]	[0.3%;48.2%]	[13.9%;68.4%]	[2.5%;100.0%]	[18.6%;55.9%]
Precaution for use: May need to stop driving or operating machinery for vision changes (Q2A)					
n (%)	5 (100.0%)	6 (66.7%)	5 (38.5%)	1 (100.0%)	17 (60.7%)
95% CI	[47.8%;100.0%]	[29.9%;92.5%]	[13.9%;68.4%]	[2.5%;100.0%]	[40.6%;78.5%]
Precaution for use: Inform your doctor of persistent or worsening changes to vision (Q2B)					
n (%)	4 (80.0%)	6 (66.7%)	11 (84.6%)	1 (100.0%)	22 (78.6%)
95% CI	[28.4%;99.5%]	[29.9%;92.5%]	[54.6%;98.1%]	[2.5%;100.0%]	[59.0%;91.7%]
Precaution for use: Doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)					
n (%)	2 (40.0%)	3 (33.3%)	8 (61.5%)	1 (100.0%)	14 (50.0%)
95% CI	[5.3%;85.3%]	[7.5%;70.1%]	[31.6%;86.1%]	[2.5%;100.0%]	[30.6%;69.4%]
Call your doctor: Light-headedness, chest discomfort, fainting (Q3A)					
n (%)	5 (100.0%)	6 (66.7%)	10 (76.9%)	1 (100.0%)	22 (78.6%)
95% CI	[47.8%;100.0%]	[29.9%;92.5%]	[46.2%;95.0%]	[2.5%;100.0%]	[59.0%;91.7%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey

Table 13: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Education Level – Completer Analysis Set (page 3 of 4)

95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.
* The variable 'Education Level' is missing for 6 patients

Table 13: Effectiveness of the XALKORI Patient Information Brochure (PIB), by Education Level – Completer Analysis Set (page 4 of 4)

	Primary School N=5	Secondary School N=9	University/Higher Education N=13	Prefer not to Answer N=1	Overall* N=28
Call your doctor: Skin and whites of your eyes turn yellow (Q3B)					
n (%)	4 (80.0%)	6 (66.7%)	8 (61.5%)	1 (100.0%)	19 (67.9%)
95% CI	[28.4%;99.5%]	[29.9%;92.5%]	[31.6%;86.1%]	[2.5%;100.0%]	[47.6%;84.1%]
Call your doctor: Urine turns dark or brown (tea colour) (Q3C)					
n (%)	3 (60.0%)	3 (33.3%)	8 (61.5%)	1 (100.0%)	15 (53.6%)
95% CI	[14.7%;94.7%]	[7.5%;70.1%]	[31.6%;86.1%]	[2.5%;100.0%]	[33.9%;72.5%]
Call your doctor: Nausea, vomiting (Q3D)					
n (%)	3 (60.0%)	6 (66.7%)	8 (61.5%)	1 (100.0%)	18 (64.3%)
95% CI	[14.7%;94.7%]	[29.9%;92.5%]	[31.6%;86.1%]	[2.5%;100.0%]	[44.1%;81.4%]
Call your doctor: Difficulties with breathing, cough, fever (Q3E)					
n (%)	5 (100.0%)	7 (77.8%)	10 (76.9%)	1 (100.0%)	23 (82.1%)
95% CI	[47.8%;100.0%]	[40.0%;97.2%]	[46.2%;95.0%]	[2.5%;100.0%]	[63.1%;93.9%]
Call your doctor: Itching, or bruised more easily than usual (Q3F)					
n (%)	3 (60.0%)	4 (44.4%)	6 (46.2%)	1 (100.0%)	14 (50.0%)
95% CI	[14.7%;94.7%]	[13.7%;78.8%]	[19.2%;74.9%]	[2.5%;100.0%]	[30.6%;69.4%]

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
95% Confidence Intervals (95% CI) for proportions are calculated using exact methods
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).
[c] The questions Q1C (Side effect: Headaches), Q1E (Side effect: Muscle pain), Q1I (Side effect: Depression) are not part of this table as these are not considered as side effects associated with XALKORI treatment. The question Q3G (Call your doctor: Tingling in fingers and feet) is not part of the table as this is not considered as a reason for calling a doctor while taking Xalkori.
* The variable 'Education Level' is missing for 6 patients

Table 14: Knowledge of Side Effects Associated with XALKORI Treatment Overall and by Country - Full Analysis Set (page 1 of 2)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Side effects associated with XALKORI treatment								
Breathing problems (Q1A)								
True	14 (35.9%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	3 (33.3%)	5 (29.4%)	0 (0.0%)	3 (75.0%)
False	12 (30.8%)	0 (0.0%)	4 (80.0%)	0 (0.0%)	1 (11.1%)	6 (35.3%)	1 (100.0%)	0 (0.0%)
I don't know	13 (33.3%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	5 (55.6%)	6 (35.3%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Abnormalities in liver blood tests (Q1B)								
True	24 (61.5%)	1 (50.0%)	3 (60.0%)	0 (0.0%)	7 (77.8%)	9 (52.9%)	0 (0.0%)	4 (100.0%)
False	4 (10.3%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	1 (11.1%)	1 (5.9%)	1 (100.0%)	0 (0.0%)
I don't know	9 (23.1%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	1 (11.1%)	5 (29.4%)	0 (0.0%)	0 (0.0%)
MD	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (11.8%)	0 (0.0%)	0 (0.0%)
Headaches (Q1C)								
True	7 (17.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (44.4%)	3 (17.6%)	0 (0.0%)	0 (0.0%)
False	17 (43.6%)	0 (0.0%)	4 (80.0%)	1 (100.0%)	5 (55.6%)	5 (29.4%)	1 (100.0%)	1 (25.0%)
I don't know	14 (35.9%)	2 (100.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	8 (47.1%)	0 (0.0%)	3 (75.0%)
MD	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)
Dizziness, light-headedness, fainting, tiredness (Q1D)								
True	27 (69.2%)	1 (50.0%)	2 (40.0%)	1 (100.0%)	8 (88.9%)	11 (64.7%)	0 (0.0%)	4 (100.0%)
False	6 (15.4%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	3 (17.6%)	1 (100.0%)	0 (0.0%)
I don't know	6 (15.4%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	1 (11.1%)	3 (17.6%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Muscle pain (Q1E)								
True	13 (33.3%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	3 (33.3%)	6 (35.3%)	0 (0.0%)	3 (75.0%)
False	12 (30.8%)	0 (0.0%)	1 (20.0%)	1 (100.0%)	5 (55.6%)	4 (23.5%)	1 (100.0%)	0 (0.0%)
I don't know	14 (35.9%)	2 (100.0%)	3 (60.0%)	0 (0.0%)	1 (11.1%)	7 (41.2%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chest discomfort or irregular heartbeat (Q1F)								
True	19 (48.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (66.7%)	10 (58.8%)	0 (0.0%)	3 (75.0%)
False	10 (25.6%)	0 (0.0%)	4 (80.0%)	0 (0.0%)	2 (22.2%)	2 (11.8%)	1 (100.0%)	1 (25.0%)
I don't know	10 (25.6%)	2 (100.0%)	1 (20.0%)	1 (100.0%)	1 (11.1%)	5 (29.4%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Changes to vision (Q1G)								
True	33 (84.6%)	1 (50.0%)	3 (60.0%)	1 (100.0%)	8 (88.9%)	16 (94.1%)	0 (0.0%)	4 (100.0%)
False	3 (7.7%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)
I don't know	2 (5.1%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)
MD	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
The correct answers are underlined

Table 14: Knowledge of Side Effects Associated with XALKORI Treatment Overall and by Country - Full Analysis Set (page 2 of 2)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Slow in heart rate (Q1H)								
True	15 (38.5%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	4 (44.4%)	7 (41.2%)	0 (0.0%)	2 (50.0%)
False	14 (35.9%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	3 (33.3%)	6 (35.3%)	1 (100.0%)	1 (25.0%)
I don't know	9 (23.1%)	1 (50.0%)	2 (40.0%)	0 (0.0%)	1 (11.1%)	4 (23.5%)	0 (0.0%)	1 (25.0%)
MD	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Depression (Q1I)								
True	5 (12.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)	3 (17.6%)	0 (0.0%)	0 (0.0%)
False	20 (51.3%)	1 (50.0%)	4 (80.0%)	1 (100.0%)	4 (44.4%)	7 (41.2%)	1 (100.0%)	2 (50.0%)
I don't know	14 (35.9%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	3 (33.3%)	7 (41.2%)	0 (0.0%)	2 (50.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
The correct answers are underlined

Table 15: Knowledge of Side Effects Associated with XALKORI Treatment Overall and by Country - Completer Analysis Set (page 1 of 2)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Side effects associated with XALKORI treatment								
Breathing problems (Q1A)								
True	12 (35.3%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	3 (42.9%)	3 (21.4%)	0 (0.0%)	3 (75.0%)
False	11 (32.4%)	0 (0.0%)	4 (80.0%)	0 (0.0%)	1 (14.3%)	5 (35.7%)	1 (100.0%)	0 (0.0%)
I don't know	11 (32.4%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	3 (42.9%)	6 (42.9%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Abnormalities in liver blood tests (Q1B)								
True	22 (64.7%)	1 (50.0%)	3 (60.0%)	0 (0.0%)	6 (85.7%)	8 (57.1%)	0 (0.0%)	4 (100.0%)
False	4 (11.8%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	1 (14.3%)	1 (7.1%)	1 (100.0%)	0 (0.0%)
I don't know	8 (23.5%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	0 (0.0%)	5 (35.7%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Headaches (Q1C)								
True	6 (17.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (42.9%)	3 (21.4%)	0 (0.0%)	0 (0.0%)
False	15 (44.1%)	0 (0.0%)	4 (80.0%)	1 (100.0%)	4 (57.1%)	4 (28.6%)	1 (100.0%)	1 (25.0%)
I don't know	13 (38.2%)	2 (100.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	7 (50.0%)	0 (0.0%)	3 (75.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Dizziness, light-headedness, fainting, tiredness (Q1D)								
True	23 (67.6%)	1 (50.0%)	2 (40.0%)	1 (100.0%)	6 (85.7%)	9 (64.3%)	0 (0.0%)	4 (100.0%)
False	5 (14.7%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	2 (14.3%)	1 (100.0%)	0 (0.0%)
I don't know	6 (17.6%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	1 (14.3%)	3 (21.4%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Muscle pain (Q1E)								
True	10 (29.4%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	2 (28.6%)	4 (28.6%)	0 (0.0%)	3 (75.0%)
False	10 (29.4%)	0 (0.0%)	1 (20.0%)	1 (100.0%)	4 (57.1%)	3 (21.4%)	1 (100.0%)	0 (0.0%)
I don't know	14 (41.2%)	2 (100.0%)	3 (60.0%)	0 (0.0%)	1 (14.3%)	7 (50.0%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Chest discomfort or irregular heartbeat (Q1F)								
True	17 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (71.4%)	9 (64.3%)	0 (0.0%)	3 (75.0%)
False	8 (23.5%)	0 (0.0%)	4 (80.0%)	0 (0.0%)	1 (14.3%)	1 (7.1%)	1 (100.0%)	1 (25.0%)
I don't know	9 (26.5%)	2 (100.0%)	1 (20.0%)	1 (100.0%)	1 (14.3%)	4 (28.6%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Changes to vision (Q1G)								
True	29 (85.3%)	1 (50.0%)	3 (60.0%)	1 (100.0%)	7 (100.0%)	13 (92.9%)	0 (0.0%)	4 (100.0%)
False	3 (8.8%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)
I don't know	2 (5.9%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
The correct answers are underlined

Table 15: Knowledge of Side Effects Associated with XALKORI Treatment Overall and by Country - Completer Analysis Set (page 2 of 2)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Slow in heart rate (Q1H)								
True	13 (38.2%)	1 (50.0%)	0 (0.0%)	1 (100.0%)	4 (57.1%)	5 (35.7%)	0 (0.0%)	2 (50.0%)
False	12 (35.3%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	2 (28.6%)	5 (35.7%)	1 (100.0%)	1 (25.0%)
I don't know	9 (26.5%)	1 (50.0%)	2 (40.0%)	0 (0.0%)	1 (14.3%)	4 (28.6%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Depression (Q1I)								
True	3 (8.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	2 (14.3%)	0 (0.0%)	0 (0.0%)
False	18 (52.9%)	1 (50.0%)	4 (80.0%)	1 (100.0%)	3 (42.9%)	6 (42.9%)	1 (100.0%)	2 (50.0%)
I don't know	13 (38.2%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	3 (42.9%)	6 (42.9%)	0 (0.0%)	2 (50.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
The correct answers are underlined

Table 16: Knowledge of Precaution for Use of XALKORI Overall and by Country - Full Analysis Set

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Precaution for use of XALKORI								
Stop driving or operating machinery if you feel that the changes to your vision prevent you from doing these activities safely (Q2A)								
True	26 (66.7%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	7 (77.8%)	13 (76.5%)	0 (0.0%)	3 (75.0%)
False	6 (15.4%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	1 (11.1%)	1 (5.9%)	1 (100.0%)	0 (0.0%)
I don't know	7 (17.9%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	1 (11.1%)	3 (17.6%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
You experience vision changes that persist, or that seem to get worse over time; there is no need to inform your doctor (Q2B)								
True	7 (17.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (33.3%)	4 (23.5%)	0 (0.0%)	0 (0.0%)
False	27 (69.2%)	1 (50.0%)	5 (100.0%)	1 (100.0%)	4 (44.4%)	11 (64.7%)	1 (100.0%)	4 (100.0%)
I don't know	5 (12.8%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)	2 (11.8%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Your doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)								
True	22 (56.4%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	7 (77.8%)	9 (52.9%)	0 (0.0%)	4 (100.0%)
False	6 (15.4%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	2 (22.2%)	2 (11.8%)	0 (0.0%)	0 (0.0%)
I don't know	11 (28.2%)	1 (50.0%)	2 (40.0%)	1 (100.0%)	0 (0.0%)	6 (35.3%)	1 (100.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
The correct answers are underlined

Table 17: Knowledge of Precaution for Use of XALKORI Overall and by Country - Completer Analysis Set

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Precaution for use of XALKORI								
Stop driving or operating machinery if you feel that the changes to your vision prevent you from doing these activities safely (Q2A)								
True	22 (64.7%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	6 (85.7%)	10 (71.4%)	0 (0.0%)	3 (75.0%)
False	6 (17.6%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	1 (14.3%)	1 (7.1%)	1 (100.0%)	0 (0.0%)
I don't know	6 (17.6%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	3 (21.4%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
You experience vision changes that persist, or that seem to get worse over time; there is no need to inform your doctor (Q2B)								
True	5 (14.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)	3 (21.4%)	0 (0.0%)	0 (0.0%)
False	26 (76.5%)	1 (50.0%)	5 (100.0%)	1 (100.0%)	4 (57.1%)	10 (71.4%)	1 (100.0%)	4 (100.0%)
I don't know	3 (8.8%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Your doctor will monitor your heart function and may adjust your XALKORI dosage (Q2C)								
True	18 (52.9%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	5 (71.4%)	7 (50.0%)	0 (0.0%)	4 (100.0%)
False	6 (17.6%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	2 (28.6%)	2 (14.3%)	0 (0.0%)	0 (0.0%)
I don't know	10 (29.4%)	1 (50.0%)	2 (40.0%)	1 (100.0%)	0 (0.0%)	5 (35.7%)	1 (100.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
The correct answers are underlined

Table 18: Knowledge of When to Call a Doctor Overall and by Country - Full Analysis Set

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Reasons for calling a doctor								
Light-headedness, chest discomfort, fainting (Q3A)								
Yes	33 (84.6%)	2 (100.0%)	2 (40.0%)	1 (100.0%)	9 (100.0%)	15 (88.2%)	0 (0.0%)	4 (100.0%)
No	2 (5.1%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	4 (10.3%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	2 (11.8%)	1 (100.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin and whites of your eyes turn yellow (Q3B)								
Yes	26 (66.7%)	2 (100.0%)	3 (60.0%)	1 (100.0%)	6 (66.7%)	10 (58.8%)	0 (0.0%)	4 (100.0%)
No	4 (10.3%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	1 (11.1%)	1 (5.9%)	0 (0.0%)	0 (0.0%)
I don't know	9 (23.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)	6 (35.3%)	1 (100.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Urine turns dark or brown (tea colour) (Q3C)								
Yes	22 (56.4%)	0 (0.0%)	2 (40.0%)	1 (100.0%)	5 (55.6%)	9 (52.9%)	1 (100.0%)	4 (100.0%)
No	9 (23.1%)	1 (50.0%)	2 (40.0%)	0 (0.0%)	2 (22.2%)	4 (23.5%)	0 (0.0%)	0 (0.0%)
I don't know	8 (20.5%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	2 (22.2%)	4 (23.5%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nausea, vomiting (Q3D)								
Yes	29 (74.4%)	0 (0.0%)	4 (80.0%)	1 (100.0%)	9 (100.0%)	12 (70.6%)	1 (100.0%)	2 (50.0%)
No	7 (17.9%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	4 (23.5%)	0 (0.0%)	1 (25.0%)
I don't know	3 (7.7%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Difficulties with breathing, cough, fever (Q3E)								
Yes	33 (84.6%)	2 (100.0%)	4 (80.0%)	1 (100.0%)	8 (88.9%)	13 (76.5%)	1 (100.0%)	4 (100.0%)
No	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (11.8%)	0 (0.0%)	0 (0.0%)
I don't know	3 (7.7%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	2 (11.8%)	0 (0.0%)	0 (0.0%)
MD	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Itching, or bruised more easily than usual (Q3F)								
Yes	21 (53.8%)	2 (100.0%)	1 (20.0%)	1 (100.0%)	6 (66.7%)	8 (47.1%)	1 (100.0%)	2 (50.0%)
No	10 (25.6%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	2 (22.2%)	5 (29.4%)	0 (0.0%)	0 (0.0%)
I don't know	7 (17.9%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	4 (23.5%)	0 (0.0%)	2 (50.0%)
MD	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Tingling in fingers and feet (Q3G)								
Yes	23 (59.0%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	7 (77.8%)	10 (58.8%)	1 (100.0%)	2 (50.0%)
No	7 (17.9%)	1 (50.0%)	2 (40.0%)	0 (0.0%)	1 (11.1%)	3 (17.6%)	0 (0.0%)	0 (0.0%)
I don't know	9 (23.1%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	1 (11.1%)	4 (23.5%)	0 (0.0%)	2 (50.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
The correct answers are underlined

Table 19: Knowledge of When to Call a Doctor Overall and by Country - Completer Analysis Set

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Reasons for calling a doctor								
Light-headedness, chest discomfort, fainting (Q3A)								
Yes	28 (82.4%)	2 (100.0%)	2 (40.0%)	1 (100.0%)	7 (100.0%)	12 (85.7%)	0 (0.0%)	4 (100.0%)
No	2 (5.9%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	4 (11.8%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	2 (14.3%)	1 (100.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Skin and whites of your eyes turn yellow (Q3B)								
Yes	24 (70.6%)	2 (100.0%)	3 (60.0%)	1 (100.0%)	6 (85.7%)	8 (57.1%)	0 (0.0%)	4 (100.0%)
No	4 (11.8%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	1 (14.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)
I don't know	6 (17.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (35.7%)	1 (100.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Urine turns dark or brown (tea colour) (Q3C)								
Yes	19 (55.9%)	0 (0.0%)	2 (40.0%)	1 (100.0%)	5 (71.4%)	6 (42.9%)	1 (100.0%)	4 (100.0%)
No	9 (26.5%)	1 (50.0%)	2 (40.0%)	0 (0.0%)	2 (28.6%)	4 (28.6%)	0 (0.0%)	0 (0.0%)
I don't know	6 (17.6%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	4 (28.6%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Nausea, vomiting (Q3D)								
Yes	24 (70.6%)	0 (0.0%)	4 (80.0%)	1 (100.0%)	7 (100.0%)	9 (64.3%)	1 (100.0%)	2 (50.0%)
No	7 (20.6%)	1 (50.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	4 (28.6%)	0 (0.0%)	1 (25.0%)
I don't know	3 (8.8%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	1 (25.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Difficulties with breathing, cough, fever (Q3E)								
Yes	29 (85.3%)	2 (100.0%)	4 (80.0%)	1 (100.0%)	7 (100.0%)	10 (71.4%)	1 (100.0%)	4 (100.0%)
No	2 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (14.3%)	0 (0.0%)	0 (0.0%)
I don't know	3 (8.8%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	2 (14.3%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Itching, or bruised more easily than usual (Q3F)								
Yes	18 (52.9%)	2 (100.0%)	1 (20.0%)	1 (100.0%)	5 (71.4%)	6 (42.9%)	1 (100.0%)	2 (50.0%)
No	10 (29.4%)	0 (0.0%)	3 (60.0%)	0 (0.0%)	2 (28.6%)	5 (35.7%)	0 (0.0%)	0 (0.0%)
I don't know	6 (17.6%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	3 (21.4%)	0 (0.0%)	2 (50.0%)
Tingling in fingers and feet (Q3G)								
Yes	19 (55.9%)	1 (50.0%)	1 (20.0%)	1 (100.0%)	5 (71.4%)	8 (57.1%)	1 (100.0%)	2 (50.0%)
No	7 (20.6%)	1 (50.0%)	2 (40.0%)	0 (0.0%)	1 (14.3%)	3 (21.4%)	0 (0.0%)	0 (0.0%)
I don't know	8 (23.5%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	1 (14.3%)	3 (21.4%)	0 (0.0%)	2 (50.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
The correct answers are underlined

Table 20: Awareness and Utilisation of Patient Information Brochure (PIB) Overall and by Country - Full Analysis Set (page 1 of 4)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Awareness, receipt, and use of the PIB								
Awareness of the XALKORI PIB prior to today (Q4)								
Yes	19 (48.7%)	2 (100.0%)	1 (20.0%)	0 (0.0%)	5 (55.6%)	9 (52.9%)	0 (0.0%)	2 (50.0%)
No	20 (51.3%)	0 (0.0%)	4 (80.0%)	1 (100.0%)	4 (44.4%)	8 (47.1%)	1 (100.0%)	2 (50.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who have been offered an external assistance to explain the PIB (Q9).
[c] Results are presented among the patients who have received the PIB (Q5), who have been offered an external assistance to explain the PIB (Q9) and who have accepted this external assistance (Q11).
[d] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).

Table 20: Awareness and Utilisation of Patient Information Brochure (PIB) Overall and by Country - Full Analysis Set (page 2 of 4)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Receipt of the XALKORI PIB (Q5)								
Yes	30 (76.9%)	2 (100.0%)	2 (40.0%)	0 (0.0%)	7 (77.8%)	16 (94.1%)	0 (0.0%)	3 (75.0%)
No	7 (17.9%)	0 (0.0%)	3 (60.0%)	1 (100.0%)	0 (0.0%)	1 (5.9%)	1 (100.0%)	1 (25.0%)
I don't know	2 (5.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If yes, **XALKORI PIB provided by doctor or another healthcare professional in the doctor's office (Q6)**[a]								
Yes	27 (90.0%)	0 (0.0%)	2 (100.0%)	0 (0.0%)	7 (100.0%)	15 (93.8%)	0 (0.0%)	3 (100.0%)
No	1 (3.3%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
XALKORI PIB obtained somewhere else	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	1 (3.3%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Amount of reading (Q7)[a]								
All of it	25 (83.3%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	5 (71.4%)	14 (87.5%)	0 (0.0%)	3 (100.0%)
Some of it	3 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
None of it	1 (3.3%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Amount of understanding (Q8)[a]								
All of it	21 (70.0%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	5 (71.4%)	10 (62.5%)	0 (0.0%)	3 (100.0%)
Some of it	6 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)	4 (25.0%)	0 (0.0%)	0 (0.0%)
None of it	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
I don't know	2 (6.7%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who have been offered an external assistance to explain the PIB (Q9).
[c] Results are presented among the patients who have received the PIB (Q5), who have been offered an external assistance to explain the PIB (Q9) and who have accepted this external assistance (Q11).
[d] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).

Table 20: Awareness and Utilisation of Patient Information Brochure (PIB) Overall and by Country - Full Analysis Set (page 3 of 4)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
External assistance to explain the XALKORI PIB (Q9)[a]								
Yes	13 (43.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (57.1%)	8 (50.0%)	0 (0.0%)	1 (33.3%)
No	15 (50.0%)	2 (100.0%)	1 (50.0%)	0 (0.0%)	3 (42.9%)	7 (43.8%)	0 (0.0%)	2 (66.7%)
I don't know	2 (6.7%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If yes, **External assistance provided by doctor of another healthcare professional in the doctor's office (Q10)[b]**								
Yes	12 (92.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (100.0%)	7 (87.5%)	0 (0.0%)	1 (100.0%)
No	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
External assistance obtained somewhere else	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)
Offer accepted (Q11)[b]								
Yes	10 (76.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	8 (100.0%)	0 (0.0%)	1 (100.0%)
No	3 (23.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (75.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If yes, **Amount of understanding from explanation (Q12)[c]**								
All of it	7 (70.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (75.0%)	0 (0.0%)	1 (100.0%)
Some of it	3 (30.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	2 (25.0%)	0 (0.0%)	0 (0.0%)
None of it	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who have been offered an external assistance to explain the PIB (Q9).
[c] Results are presented among the patients who have received the PIB (Q5), who have been offered an external assistance to explain the PIB (Q9) and who have accepted this external assistance (Q11).
[d] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).

Table 20: Awareness and Utilisation of Patient Information Brochure (PIB) Overall and by Country - Full Analysis Set (page 4 of 4)

	Overall N=39	Austria N=2	Belgium N=5	France N=1	Germany N=9	Italy N=17	Netherlands N=1	Sweden N=4
Knowledge of the presence of a patient ID card (Q13)[a]								
Yes	14 (46.7%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	5 (71.4%)	5 (31.3%)	0 (0.0%)	1 (33.3%)
No	9 (30.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)	5 (31.3%)	0 (0.0%)	2 (66.7%)
I don't know	7 (23.3%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (37.5%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If yes, Use of patient ID card by telling other doctors receiving XALKORI treatment (Q14)[d]								
Yes	3 (21.4%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)
No	10 (71.4%)	0 (0.0%)	2 (100.0%)	0 (0.0%)	5 (100.0%)	2 (40.0%)	0 (0.0%)	1 (100.0%)
I don't know	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Full Analysis Set is defined as all eligible patients who have completed at least 1 main question (questions 1-14)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who have been offered an external assistance to explain the PIB (Q9).
[c] Results are presented among the patients who have received the PIB (Q5), who have been offered an external assistance to explain the PIB (Q9) and who have accepted this external assistance (Q11).
[d] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).

Table 21: Awareness and Utilisation of Patient Information Brochure (PIB) Overall and by Country - Completer Analysis Set (page 1 of 4)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Awareness, receipt, and use of the PIB								
Awareness of the XALKORI PIB prior to today (Q4)								
Yes	18 (52.9%)	2 (100.0%)	1 (20.0%)	0 (0.0%)	4 (57.1%)	9 (64.3%)	0 (0.0%)	2 (50.0%)
No	16 (47.1%)	0 (0.0%)	4 (80.0%)	1 (100.0%)	3 (42.9%)	5 (35.7%)	1 (100.0%)	2 (50.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who have been offered an external assistance to explain the PIB (Q9).
[c] Results are presented among the patients who have received the PIB (Q5), who have been offered an external assistance to explain the PIB (Q9) and who have accepted this external assistance (Q11).
[d] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).

Table 21: Awareness and Utilisation of Patient Information Brochure (PIB) Overall and by Country - Completer Analysis Set (page 2 of 4)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Receipt of the XALKORI PIB (Q5)								
Yes	26 (76.5%)	2 (100.0%)	2 (40.0%)	0 (0.0%)	6 (85.7%)	13 (92.9%)	0 (0.0%)	3 (75.0%)
No	7 (20.6%)	0 (0.0%)	3 (60.0%)	1 (100.0%)	0 (0.0%)	1 (7.1%)	1 (100.0%)	1 (25.0%)
I don't know	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If yes, XALKORI PIB provided by doctor or another healthcare professional in the doctor's office (Q6)[a]								
Yes	24 (92.3%)	0 (0.0%)	2 (100.0%)	0 (0.0%)	6 (100.0%)	13 (100.0%)	0 (0.0%)	3 (100.0%)
No	1 (3.8%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
XALKORI PIB obtained somewhere else	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	1 (3.8%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Amount of reading (Q7)[a]								
All of it	22 (84.6%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	4 (66.7%)	12 (92.3%)	0 (0.0%)	3 (100.0%)
Some of it	3 (11.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
None of it	1 (3.8%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Amount of understanding (Q8)[a]								
All of it	20 (76.9%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	5 (83.3%)	9 (69.2%)	0 (0.0%)	3 (100.0%)
Some of it	4 (15.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	3 (23.1%)	0 (0.0%)	0 (0.0%)
None of it	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
I don't know	1 (3.8%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who have been offered an external assistance to explain the PIB (Q9).
[c] Results are presented among the patients who have received the PIB (Q5), who have been offered an external assistance to explain the PIB (Q9) and who have accepted this external assistance (Q11).
[d] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).

Table 21: Awareness and Utilisation of Patient Information Brochure (PIB) Overall and by Country - Completer Analysis Set (page 3 of 4)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
External assistance to explain the XALKORI PIB (Q9)[a]								
Yes	11 (42.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (66.7%)	6 (46.2%)	0 (0.0%)	1 (33.3%)
No	14 (53.8%)	2 (100.0%)	1 (50.0%)	0 (0.0%)	2 (33.3%)	7 (53.8%)	0 (0.0%)	2 (66.7%)
I don't know	1 (3.8%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If yes, External assistance provided by doctor of another healthcare professional in the doctor's office (Q10)[b]								
Yes	10 (90.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (100.0%)	5 (83.3%)	0 (0.0%)	1 (100.0%)
No	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
External assistance obtained somewhere else	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)
Offer accepted (Q11)[b]								
Yes	8 (72.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	6 (100.0%)	0 (0.0%)	1 (100.0%)
No	3 (27.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (75.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If yes, Amount of understanding from explanation (Q12)[c]								
All of it	6 (75.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (83.3%)	0 (0.0%)	1 (100.0%)
Some of it	2 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)
None of it	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
I don't know	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who have been offered an external assistance to explain the PIB (Q9).
[c] Results are presented among the patients who have received the PIB (Q5), who have been offered an external assistance to explain the PIB (Q9) and who have accepted this external assistance (Q11).
[d] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).

Table 21: Awareness and Utilisation of Patient Information Brochure (PIB) Overall and by Country - Completer Analysis Set (page 4 of 4)

	Overall N=34	Austria N=2	Belgium N=5	France N=1	Germany N=7	Italy N=14	Netherlands N=1	Sweden N=4
Knowledge of the presence of a patient ID card (Q13)[a]								
Yes	12 (46.2%)	1 (50.0%)	2 (100.0%)	0 (0.0%)	5 (83.3%)	3 (23.1%)	0 (0.0%)	1 (33.3%)
No	8 (30.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	5 (38.5%)	0 (0.0%)	2 (66.7%)
I don't know	6 (23.1%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (38.5%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
If yes, Use of patient ID card by telling other doctors receiving XALKORI treatment (Q14)[d]								
Yes	2 (16.7%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)
No	9 (75.0%)	0 (0.0%)	2 (100.0%)	0 (0.0%)	5 (100.0%)	1 (33.3%)	0 (0.0%)	1 (100.0%)
I don't know	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)
MD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Completer Analysis Set is defined as all eligible patients who have completed all core questions (questions 1A-1I, 2A-2C, 3A-3G, 4, 5 and 13)
Ireland, Denmark, and United Kingdom were not included in the table because no patients responded to the patient survey
MD=Missing data
[a] Results are presented among the patients who have received the PIB (Q5).
[b] Results are presented among the patients who have received the PIB (Q5) and who have been offered an external assistance to explain the PIB (Q9).
[c] Results are presented among the patients who have received the PIB (Q5), who have been offered an external assistance to explain the PIB (Q9) and who have accepted this external assistance (Q11).
[d] Results are presented among the patients who have received the PIB (Q5) and who know that there is a patient ID card in the PIB (Q13).

Table 22: Physicians with the Number of Patients Completed Survey Overall and By Country

	Number of Physicians Participating in the Survey										
	Overall* N=126	Austria N=13	Belgium N=4	Denmark N=10	France N=21	Germany N=42	Ireland N=3	Italy N=9	Netherlands N=10	Sweden N=4	United Kingdom N=10
Number of patients included per participating physician											
Any	15 (11.9%)	1 (7.7%)	4 (100.0%)	0 (0.0%)	1 (4.8%)	3 (7.1%)	0 (0.0%)	4 (44.4%)	1 (10.0%)	1 (25.0%)	0 (0.0%)
1	5 (4.0%)	0 (0.0%)	3 (75.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)
2	2 (1.6%)	1 (7.7%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
≥3	8 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (7.1%)	0 (0.0%)	4 (44.4%)	0 (0.0%)	1 (25.0%)	0 (0.0%)
N	126	13	4	10	21	42	3	9	10	4	10
Mean (SD)	0.3 (1.0)	0.2 (0.6)	1.3 (0.5)	0.0 (0.0)	0.0 (0.2)	0.2 (0.8)	0.0 (0.0)	2.0 (2.4)	0.1 (0.3)	1.0 (2.0)	0.0 (0.0)
Median	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Q1-Q3	0 - 0	0 - 0	1 - 2	0 - 0	0 - 0	0 - 0	0 - 0	0 - 4	0 - 0	0 - 2	0 - 0
Minimum-Maximum	0 - 5	0 - 2	1 - 2	0 - 0	0 - 1	0 - 3	0 - 0	0 - 5	0 - 1	0 - 4	0 - 0

SD=Standard deviation
* 126 physicians are considered in this table:
- 120 physicians involved in the physician survey. Among them only 9 were involved in the patient survey.
- 6 physicians not involved in the physician survey and involved in the patient survey: 1 in Netherlands (1 patient), 2 in Belgium (3 patients), 1 in Italy (4 patients) and 2 in Germany (6 patients)