
SPONSOR SIGNATURE

Title of study:

Healthcare Professional and Patient Surveys to Evaluate the Effectiveness of the Risk Minimisation Educational Materials for Certolizumab Pegol (CZP; CIMZIA®)

Author of report:

██████████, Impact Pharmaceutical Services, Inc.

I have read this study report and confirm that to the best of my knowledge it accurately describes the conduct and results of the noninterventional postauthorization safety study.

Name: ██████████ and ██████████

Affiliation: UCB Biopharma SPRL

Signature:

Date:

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NON-INTERVENTIONAL POST-AUTHORIZATION SAFETY STUDY (PASS) FINAL STUDY REPORT UP0038

PASS INFORMATION

Title	Healthcare Professional and Patient Surveys to Evaluate the Effectiveness of the Risk Minimisation Educational Materials for Certolizumab Pegol (CZP; CIMZIA®)
Version identifier of the final clinical study report	1.0
Date of last version of the final clinical study report	17 Oct 2019
European Post-Authorization Study (PAS) register number	EUPAS14867
Active substance	CZP (tumor necrosis factor [TNF] alpha inhibitor; L04AB05)
Medicinal product	CZP (CIMZIA®)
Product reference	Not applicable
Procedure number	EMA/H/C/001037
Marketing authorization holder	UCB Biopharma SPRL
Joint PASS	No
Research question and objectives	<p>The overall objective of this study was to evaluate the effectiveness of the risk minimization measures being implemented in the EU: Patient and healthcare provider educational program.</p> <p>Surveys were used to assess the effectiveness of the risk minimization methods. The aims of the surveys were to:</p> <ul style="list-style-type: none"> • Evaluate the effectiveness of the CZP Risk Management Plan (RMP) educational program in achieving its goals by measuring patient knowledge and understanding of the serious risks associated with CZP. • Measure healthcare providers' knowledge of the serious risks associated with the use of CZP, proper prescribing of the product, and proper monitoring for the key risks associated with the use of CZP.

Title	Healthcare Professional and Patient Surveys to Evaluate the Effectiveness of the Risk Minimisation Educational Materials for Certolizumab Pegol (CZP; CIMZIA®)
Countries of study	This study was conducted in 7 countries: Denmark, France, Germany, Greece, Norway, Sweden, and the United Kingdom.
Author	██████████, Impact Pharmaceutical Services, Inc.
Sponsor Safety Lead	██████████

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MARKETING AUTHORIZATION HOLDER

Marketing authorization holder	UCB Biopharma SPRL Allée de la Recherche 60 B-1070 Brussels Belgium
MAH contact person	██████████ Safety Lead, CIMZIA® ████████████████████

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1 ABSTRACT

Name of company: UCB Biopharma, SPRL	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Cimzia®	Volume: Not applicable	
Name of active ingredient: Certolizumab pegol	Page: Not applicable	
Title: Healthcare Professional and Patient Surveys to Evaluate the Effectiveness of the Risk Minimisation Educational Materials for Certolizumab Pegol (CZP; CIMZIA®)		
Date: 17 Oct 2019		
Main author and affiliation: ██████████, IMPACT Pharmaceutical Services		
Keywords: Certolizumab pegol, CIMZIA®, noninterventional study (NIS), post-authorization safety study (PASS), and effectiveness of educational materials		
Rationale and background: The Risk Minimization Educational Materials for CZP are a suite of materials developed for prescribing physicians, other healthcare professionals (HCPs), and patients to enhance the communication of key safety and prescribing information for CZP. The educational materials provide information on the safety concerns of CZP and on the measures used to mitigate them. This study consisted of surveys that assessed the effectiveness of the educational materials.		
Research question and objectives: The overall objective of this study was to evaluate the effectiveness of the educational material risk minimization measures being implemented in the EU in HCPs who were prescribing and/or administering CZP and in patients who were prescribed CZP.		
Study design: This PASS was conducted by means of a cross-sectional survey of a sample of HCPs and patients in Denmark, France, Germany, Greece, Norway, Sweden, and the UK. Two surveys were used for the qualitative collection of data, and these were administered locally: a HCP survey (for use with prescribing physicians and HCPs who administer CZP) and a patient survey (for use with patients who have received CZP).		
Setting: The target population for the HCP survey was HCPs who had prescribed or monitored patients who received treatment with CZP and who had not previously completed a survey regarding the risks of CZP. The target population for the patient survey was patients who had not previously participated in any surveys about the educational tools for CZP and who had received at least 1 prescription of CZP within the last 6 months.		
Study participants and study size, including dropouts: The recommended sample size for each European country included in this study was 40 HCPs (rheumatologists and rheumatology nurses) and 20 patients. For Denmark, Sweden, and Norway, a smaller sample size was used (Nordic combined sample: 40 HCPs and 15 patients).		

Name of company: UCB Biopharma, SPRL	Individual study table referring to part of the dossier: Not applicable	<i>(For National Authority Use Only)</i>
Name of finished product: Cimzia®	Volume: Not applicable	
Name of active ingredient: Certolizumab pegol	Page: Not applicable	
<p>Variables: The primary outcome of these surveys was the proportion of respondents who received, were aware of, or accessed each of the CZP educational materials (Patient Alert Card and Prescriber Guide) reported as:</p> <ul style="list-style-type: none"> • A summary of correct responses to each individual question on the understanding of the potential risks associated with CZP treatment (HCP survey). • A summary of correct responses to each question regarding CZP risks (patient survey). 		
<p>Data sources: Responses to the HCP and patient surveys were analysed in order to calculate the percentage of correct responses to the individual questions on the understanding of the potential risks associated with CZP treatment.</p>		
<p>Results:</p> <p>This PASS study was conducted by means of a cross-sectional survey of a sample of HCP respondents and patient respondents in Denmark, France, Germany, Greece, Norway, Sweden, and the UK.</p> <p>The overall objective of this study was to evaluate the effectiveness of the educational material risk minimization measures being implemented in the EU in HCP respondents who were prescribing and/or administering CZP and in patient respondents who were prescribed CZP.</p> <p>Two surveys were used for the qualitative collection of data, and these were administered locally:</p> <ul style="list-style-type: none"> • Healthcare professional survey – for use with prescribing physicians and HCP respondents who administered CZP • Patient survey – for use with patient respondents who had received CZP <p>CZP educational materials receipt, awareness, access, and understanding</p> <ul style="list-style-type: none"> • Healthcare professional respondents <ul style="list-style-type: none"> – The majority of HCP respondents in France (73%), Germany (100%), the UK (74%), and Greece (96%) received the CZP Prescriber guide, though receipt was lower in the Nordics (44%). In each country, the proportion of HCP respondents who received the CZP Prescriber Guide was above or within the European Medicines Agency (EMA) usage target of 35% to 60%. – Of the HCP respondents who read the CZP prescriber guide (89%), a majority understood (97%) the CZP Prescriber guide overall and by country for France (91% and 95%, respectively), Germany (100% each), the UK (84% and 95%, respectively), Greece (96% and 100%, respectively), and the Nordics (84% and 96%, respectively). – Overall, the CZP Prescriber Guide was well understood with 164 HCP respondents (97%) understanding all information. The proportions of HCP respondents who understood all information in the CZP Prescriber Guide were high and similar between countries ($\geq 95\%$ in each country). 		

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Name of finished product: Cimzia®	Volume: Not applicable	
Name of active ingredient: Certolizumab pegol	Page: Not applicable	
<ul style="list-style-type: none"> – Overall, 113 HCP respondents (67%) indicated they received the Patient Alert Card. In individual countries, the proportions of HCP respondents who indicated they received the Patient Alert Card were higher in Germany (25 HCP respondents [96%]) and Greece (34 HCP respondents [85%]) compared with France (18 HCP respondents [45%]) and the UK (22 HCP respondents [55%]). – Overall, the proportion of HCP respondents who read the Patient Alert Card was high (107 HCP respondents [95%]). The majority of HCP respondents thought that the Patient Alert Card was extremely useful (18 HCP respondents [11%]) or very useful (81 HCP respondents [48%]). • Patient respondents <ul style="list-style-type: none"> – In total, 73% of patient respondents received the Patient Alert Card, including 52% of patient respondents in France, 100% of patient respondents in Germany, 75% of patient respondents in the UK, 88% of patient respondents in Greece, and 52% of patient respondents in the Nordics, which was above the EMA usage target of 35% to 50% in each country. – Overall, the proportion of patient respondents who read the Patient Alert Card was high (91%), and ranged from 100% in the UK and the Nordics to 88% in Germany, which was above the EMA target of 35% to 50%. The proportion of patient respondents who indicated they understood all the information displayed in the Patient Alert Card for CZP was high (61 patient respondents [97%]), and ranged from 2 patient respondents (100%) in the Nordics to 14 patient respondents (93%) in Germany. <p>Knowledge related to important CZP safety information</p> <ul style="list-style-type: none"> • Healthcare professional respondents <ul style="list-style-type: none"> – In general, the majority of HCP respondents were able to correctly identify which risks were and were not associated with CZP. The most common correctly identified risk that was associated with CZP was serious bacterial infection (149 HCP respondents [88%]). – Overall, the proportions of HCP respondents who correctly answered questions regarding the use of CZP with ‘True’ was high and ranged from 162 HCP respondents (96%) to 144 HCP respondents (85%). The proportions of HCP respondents who correctly answered questions regarding the use of CZP as ‘False’ ranged from 121 HCP respondents (72%) to 56 HCP respondents (33%). • Patient respondents <ul style="list-style-type: none"> – The majority of patient respondents were able to correctly respond to each statement about CZP (range: 61 patient respondents [97%] to 41 patient respondents [65%]). The most common correctly identified statement was ‘You have to contact your doctor in case of persistent fever or infection’ (response of ‘True’) (61 patient respondents [97%]). 		

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Name of finished product: Cimzia®	Volume: Not applicable	
Name of active ingredient: Certolizumab pegol	Page: Not applicable	
Conclusions: The results of this PASS showed that the majority of HCP respondents and patient respondents read and understood all information that provided guidance on the safety profile and safe use of CZP. Furthermore, the percentage of respondents was within the target values agreed with EMA. The majority of HCP respondents and patient respondents also found these materials useful or helpful in understanding the safety profile of CZP.		
Marketing Authorization Holder UCB Biopharma SPRL		
Names and affiliations of Principal Investigators There was no Principal or Coordinating Investigator for this study; the surveys were distributed by Kantar Health to the various EU countries in which the effectiveness of the educational materials was being assessed.		

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2 LIST OF ABBREVIATIONS

AE	adverse event
CAWI	computer-aided web interview
CZP	certolizumab pegol (CIMZIA [®])
EMA	European Medicines Agency
DIR	directive
HBV	hepatitis B virus
HCP	healthcare professional
ISO	International Standard for Market Research
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
PAS	postauthorization study
PASS	postauthorization safety study
PRAC	Pharmacovigilance Risk Assessment Committee
RMP	Risk Management Plan
TB	tuberculosis
TNF	tumor necrosis factor

3 INVESTIGATORS

There was no Principal or Coordinating Investigator for this study; this postauthorization safety study (PASS) was sponsored by UCB and conducted by Kantar Health. The surveys were distributed by Kantar Health to the various EU countries in which the effectiveness of the educational materials was being assessed.

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4 OTHER RESPONSIBLE PARTIES

Although this study did not evaluate safety, there was an option for respondents to report any adverse events (AEs). Furthermore, there were designated safety contacts from UCB by country and a Central Safety Contact from Kantar Health for AE reporting during the conduct of this study.

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5 MILESTONES

The important milestones of the study are presented [Table 5-1](#).

Table 5-1: Important study milestones

Milestone	Planned date	Actual date
Start of data collection	01 Aug 2016	01 Aug 2016
End of data collection	31 Jul 2019	31 Jul 2019
Registration in the EU PASS Register	30 Aug 2016	30 Aug 2016
Final report of study results	30 Nov 2019	17 Oct 2019

6 RATIONALE AND BACKGROUND

The Risk Minimization Educational Materials for certolizumab pegol (CZP; Cimzia®) are a suite of materials developed for prescribing physicians, other healthcare professionals (HCPs), and patients to enhance the communication of key safety and prescribing information for CZP.

The educational materials provide information on the safety concerns of CZP and on the measures used to mitigate them. These educational materials are a component of the overall EU-Risk Management Plan (RMP) for CZP, approved by the European Medicines Agency (EMA), and UCB committed to the development and distribution of the educational materials as part of the Marketing Authorisation Application (MAA). The details of the risk minimization materials for the program and how these have been implemented in the EU are described in the RMP.

The effectiveness evaluation methods consisted of a quantitative assessment and a qualitative assessment involving sample surveys of HCPs (ie, prescribing physicians and HCPs who administered CZP) and patients who have received CZP. As per EU regulations, the effectiveness of the risk minimization measures must be assessed on an ongoing basis.

The Prescriber Guide provided to HCPs for CZP focused on informing about risks that are overall shared with those of other tumor necrosis factor (TNF) inhibitors, which have been used for several years. The experience with the use of other TNF inhibitors provided an adequate level of understanding of the potential risks and management thereof. During the conduct of this PASS, the distribution of the Prescriber Guide and the HCP survey was stopped based on Pharmacovigilance Risk Assessment Committee (PRAC) feedback and in line with the agreed RMP v14.1 (procedure EMEA/H/C/001037/II/0072, positive opinion dated 17 Jan 2019).

The approach to collecting qualitative information is provided in [Table 6-1](#) and is the focus of the surveys analyzed in this study.

Table 6-1: Educational materials – qualitative evaluation methods

Tool	Metric	Method	Target Values (agreed with EMA)	Timing
Prescribing physician and HCP tools	Estimated proportion of directly contacted prescribing physicians who have used the educational tools	Sample survey of prescribing physicians who have been contacted	35% to 60%	18 months post launch then annually after first data collection
Prescribing physician and HCP tools	Prescribing physicians and HCPs who administer CZP – feedback on real-world usage and potential improvements	Qualitative sample survey of prescribing physicians and HCPs. Participants will be asked about their usage of the tools, perceived effectiveness of the tools and suggestions for improvement.	Not applicable	18 months post launch then annually after first data collection
Patient Alert Card ^a	Estimated proportion of patients who have received/used the patient alert card ^a	Sample survey of patients	35% to 50%	18 months post launch then annually after first data collection
Patient Alert Card ^a	Patient feedback on real-world usage and potential improvements	Qualitative sample survey of patients. Participants will be asked about their usage of the tools, perceived effectiveness of the tools and suggestions for improvement.	50% to 80% (patients who have used the alert card)	18 months post launch then annually after first data collection

CZP=certolizumab pegol; EMA=European Medicines Agency; HCP=healthcare professional; MAH=Marketing Authorisation Holder; PRAC=Pharmacovigilance Risk Assessment Committee; RMP=Risk Management Plan

^a Based on PRAC feedback and the corresponding updates introduced in RMP v14.1 (procedure EMEA/H/C/001037/II/0072, positive opinion dated 17 Jan 2019), the MAH intends to rename Patient Alert Card to Patient Reminder Card at the next update of the card's contents.

Previous versions of the surveys are described in Section 7 of the protocol.

Postauthorization Safety Study

In accordance with the PASS definition (“Post-authorisation safety study: Any study relating to an authorized medicinal product conducted with the aim of identifying, characterising or

quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures") in Directive 2001/83/EC (DIR) Art 1(15), UCB has conducted a PASS in order to assess the effectiveness of the CZP RMP Educational Materials.

Updated versions of the surveys were used in this study to assess the current levels of patient and HCP knowledge of the key risks associated with CZP following the distribution of the updated educational materials (Version 4.0, distributed from February 2015).

Due to local adaptation of the materials and National Health Authorities approvals, the distribution dates varied from country to country. UCB conducted this PASS 18 months postdistribution of the Educational Materials in the 7 countries (Denmark, France, Germany, Greece, Norway, Sweden, and the UK).

7 RESEARCH QUESTION AND OBJECTIVES

The overall objective of this study was to evaluate the effectiveness of the education material risk minimization measures that were implemented in the EU in patients who were prescribed CZP.

Specifically, the objectives of the surveys were to:

- Measure HCPs' knowledge of the serious risks associated with the use of CZP, proper prescribing of the product, and proper monitoring for the key risks associated with the use of CZP.
- Evaluate the effectiveness of the CZP RMP educational program in achieving its goals by measuring patient knowledge and understanding of the key risks associated with CZP.

The distribution of the Prescriber Guide and the HCP survey was stopped based on PRAC feedback and in line with the agreed RMP v14.1. Hence, no further data was collected on this study objective.

8 AMENDMENTS AND UPDATES

The original final protocol was amended twice. Protocol Amendment 1 was prepared in support of RMP v14 (Procedure number: EMEA/H/C/001037/II/0072). This amendment was not submitted to any of the participating countries as additional feedback from EMA was received during the procedure requesting additional updates. Protocol Amendment 2 included these additional updates based on PRAC feedback and the corresponding updates introduced in RMP v14.1, and received a positive opinion on 17 Jan 2019. Details of the changes implemented in the protocol amendments are presented in [Table 8-1](#).

Table 8-1: Protocol amendments

Section of protocol changed	Amendment or update	Reason
Amendment 1 (11 Jul 2018)		
PASS Information; Section 4	Updated date of last version of protocol: 11 July 2018.	New amendment date added.
PASS Information	Added EU PAS register number EUPAS14867.	New information added.
PASS Information	Updated Research Objectives to match body text.	Updated to provide consistency within the document.
PASS Information; Section 4; Section 7; Section 9.1; Table 2	Removed Italy and Spain. Updated text to note PASS conducted according to local regulations.	For compliance reasons, PASS was not feasible in Spain and Italy.
PASS Information	Updated MAH Contact Person.	MAH contact information was outdated and was updated.
Section 4; Section 9.5; Table 2	Dermatologists added to HCP study population; indications expanded.	Dermatologists added to include a new audience of prescribers with the newly approved psoriasis indication.
Section 4; Section 6	Updated dates for end of data collection, final report of study results, and Registration in EU PAS register.	Milestones were outdated and were updated.
Section 7	Reference to sections of the RMP removed.	RMP template has been updated and these sections as listed are no longer correct.
Section 9.2	Males and females added.	Clarification of study population.
Section 11	Removed text under "Reconciliation".	Text removed to clarify reconciliation of reporting was done at the end of the program.
Annex 2	Safety contact information updated.	Contact information was outdated and was updated.
Annex 3	New version of ENCePP checklist added.	A new version of the checklist was completed.
Throughout	Clarifications made throughout document including minor rewording and correction of typographical errors.	Updated to provide consistency within the document.
Amendment 2 (17 Jan 2019)		
PASS Information; Section 4	Identifier and date of last version of protocol: 3.0-17 Jan 2019	New identifier and amendment date added.

Table 8-1: Protocol amendments

Section of protocol changed	Amendment or update	Reason
Section 4; Section 9.5	Clarification that dermatologists were not surveyed.	With approval of RMP v14.1, the distribution of the Prescriber Guide was stopped. Consequently, HCP surveys have ceased, and the addition of dermatologists was no longer relevant.
Section 7	Rationale that the experience with the use of TNF inhibitors provided an adequate level of understanding to HCPs and the issuance of the Prescriber Guide was no longer necessary has been added.	Change based on PRAC feedback and in line with the agreed RMP v14.1 (procedure EMEA/H/C/001037/II/0072, positive opinion dated 17 Jan 2019).
Section 7; Section 8; Section 9.5; Section 9.7	The distribution of the Prescriber Guide and the HCP survey ceased upon the approval of RMP v14.1.	Change based on PRAC feedback and in line with the agreed RMP v14.1 (procedure EMEA/H/C/001037/II/0072, positive opinion dated 17 Jan 2019).
Table 1; Section 9.3	Patient Alert Card will be renamed to Patient Reminder Card at the next update of the card's contents.	Change based on PRAC feedback and in line with the agreed RMP v14.1 (procedure EMEA/H/C/001037/II/0072, positive opinion dated 17 Jan 2019).
Section 9.1	Text has been included regarding the amendment history of the protocol.	Clarification of the purpose and use of the different protocol versions.
Section 9.5	The sample size of each European country and Nordic combined sample of 40 HCPs was not met.	With approval of RMP v14.1, the distribution of the Prescriber Guide was stopped. Consequently, HCP surveys have ceased.
Section 9.7	All data from the HCP surveys collected up to the point of approval of RMP v14.1 were analyzed.	With approval of RMP v14.1, the distribution of the Prescriber Guide was stopped. Consequently, HCP surveys have ceased.
Throughout	Clarifications have been made including minor rewording and correction of typographical errors.	Provided consistency within the document.

ENCePP=European Network of Centres for Pharmacoepidemiology and Pharmacovigilance; HCP=healthcare professional; MAH=Marketing Authorisation Holder; PAS=post-authorisation study; PASS=post-authorisation safety study; PRAC=Pharmacovigilance Risk Assessment Committee; RMP=Risk Management Plan; TNF=tumour necrosis factor

9 RESEARCH METHODS

9.1 Study design

This PASS study was conducted with the aim to evaluate the effectiveness of the CZP risk minimization educational materials being implemented in the EU. The study was conducted by means of a cross-sectional survey of a sample of HCPs and patients in Denmark, France, Germany, Greece, Norway, Sweden, and the UK.

Two surveys were used for the qualitative collection of data, and these were administered locally:

- Healthcare professional survey – for use with prescribing physicians and HCPs who administered CZP
- Patient survey – for use with patients who had received CZP

The survey took approximately 15 minutes for respondents to complete and was offered online only (computer-aided web interview [CAWI]), except where there were local restrictions (eg, in Greece, where patients were interviewed by telephone; their answers were entered online via a unique web link). Online surveys allowed flexibility, so that the HCP or patient could have completed the survey at a time most convenient to them. Each survey was composed of multiple-choice and open- and close-ended questions.

9.2 Setting

The survey was conducted in Denmark, France, Germany, Greece, Norway, Sweden, and the United Kingdom. In order to identify HCPs and patients who were suitable for this study, HCPs were contacted by using local networks, and the HCPs then contacted patients that may have been eligible for this study. The recruitment processes varied between individual countries as outlined in Protocol Section 9.2. The HCPs and patients selected were then sent the survey. The initial questions identified whether the respondent met the inclusion criteria for this study; if the respondent was not suitable the survey was automatically ended and the respondent was excluded from the study. These criteria are outlined in Section 9.3.

9.3 Study participants

The population for the HCP survey was:

- HCPs who have prescribed or monitored patients receiving treatment with CZP
- HCPs who have not previously completed a survey regarding the risks of CZP

The population for the patient survey was:

- Patients who were male or female and were ≥ 18 years of age
- Patients who had not previously participated in any surveys about the educational tools for CZP
- Patients who had received ≥ 1 prescription of CZP within the last 6 months
- Patients who were not HCPs themselves (eg, a doctor, nurse, pharmacist)

9.4 Variables

The primary variable for the surveys was the proportion of respondents who received, were aware of, or accessed each of the CZP educational materials (Patient Alert Card and Prescriber Guide).

As agreed with EMA in RMP v14.1 (procedure number EMEA/H/C/001037/II/0072, positive opinion dated 17 Jan 2019), the Patient Alert Card will be renamed to Patient Reminder Card at the next update of the card's contents; therefore, this change did not impact the study.

9.5 Data sources and measurement

The responses to the HCP and patient surveys were analysed. The percentages of correct responses to each individual question on the understanding of the potential risks associated with CZP treatment, from both the HCP and patient respondent surveys, were calculated.

9.6 Bias

To minimize the potential for nonresponse, respondents were paid to take part in this study (patients in France were not paid, in line with UCB's Incentives Policy). Respondents had a sufficient period of time to complete the survey (HCPs: 5 weeks; patients: 6 weeks).

Other potential limitations of the research methods include:

- Patient recruitment process/patient referral process by HCPs can be slow; therefore, 6 weeks were allowed for recruitment.
- HCPs in the area of Rheumatology and Biologics are a highly researched population currently, and this may have affected the level of response.
- Sample size
 - The sample size for the original surveys in Europe was generated based on the sample size utilized in a comparable exercise in the US conducted as part of the Risk Evaluation and Mitigation Strategy for CZP.
 - In the US, a total of 250 HCP respondents completed the survey to assess the effectiveness of the US educational materials. It was estimated that there was a total of 5000 HCPs prescribing CZP in the US.
 - Based on a consideration of population size, it was therefore considered appropriate to assess a similar number of physicians/HCP respondents (N=250) and patient respondents (N=250) within the EU.
 - The recommended sample size for each European country included in this study was therefore 40 HCP respondents (rheumatologists and rheumatology nurses) and 20 patient respondents. For Denmark, Sweden, and Norway these numbers were not practical, so a smaller sample size was used (Nordic combined sample: 40 HCP respondents and 15 patient respondents).
 - The distribution of the Prescriber Guide and the HCP survey was stopped based on PRAC feedback and in line with the agreed RMP v14.1. Due to the premature completion

of this part of the study, the sample size of each European country of 40 HCP respondents was not met.

9.7 Data transformation

Not applicable.

9.8 Statistical methods

To evaluate HCPs' knowledge of the CZP educational materials, 2 analyses were performed.

- A summary of the percentage of HCP respondents who received, were aware of, or accessed each of the CZP educational materials and to what extent those materials were read
- A summary of correct responses to each individual question on the understanding of CZP

In order to evaluate patients' knowledge of the CZP educational materials program, 2 analyses were performed:

- A presentation of the percentage of patient respondents who received, were aware of, or accessed the CZP educational materials and to what extent those materials were read and understood
- A summary of correct responses to each question regarding CZP risks

The target values that were agreed to with the EMA for the number of HCP respondents and patient respondents using educational materials are described in [Table 6-1](#).

9.8.1 Main summary measures

Not applicable.

9.8.2 Main statistical methods

Not applicable.

9.8.3 Methods used to examine subgroups and interactions

Not applicable.

9.8.4 Missing values

Not applicable.

9.8.5 Sensitivity analyses

Not applicable.

9.9 Quality control

Kantar Health has received ISO 20252:2012 (International Standard for Market Research) accreditation, which has strict standards on data quality, integrity, and protection (Certification Number 1019). Kantar Health's global quality and compliance team ensured the research in this study met this standard and abided by market research codes of conduct (MRS, EphmRA and BHBIA), which covers steps to ensure data quality, data integrity, and data protection. This also applied to Kantar Health's fieldwork partners, who recruited respondents.

All HCPs underwent checks before they were included in the fieldwork partner’s panels (ie, to ensure they were a qualified HCP), and in the case of both patients and HCPs, these were screened using criteria set by UCB to ensure they were eligible to take part in the survey.

Quality control checks began at the soft launch stage (ie, after the initial interviews were completed) ahead of fully starting the survey to confirm if answers were being recorded for all questions as expected and that the online survey was working correctly. Upon study completion, quality checks on the raw data were completed (eg, looking for respondents who completed the survey too quickly, who pattern answered, who have nonsense answers to open-ended questions) and any unsuitable respondents were removed from the data (and, replaced if possible).

Data tables underwent internal quality control. All data (questionnaires, raw data, and tabulations) were stored on a secure server by Kantar Health and UCB.

10 RESULTS

10.1 Participants

The actual start and end dates for data collection are presented by country in [Table 10-1](#). Due to the small number of patient and HCP respondents in each of Sweden, Denmark, and Norway, data from these countries have been pooled and are presented in this Final Study Report under the heading of Nordics. Data collection started (01 Aug 2016) and ended (31 Jul 2019) as planned per protocol ([Table 5-1](#)).

Table 10-1: Start and end dates for data collection by country

Countries	Patient respondents		HCPs respondents	
	Date fieldwork started	Date fieldwork ended	Date fieldwork started	Date fieldwork ended
France	15 Nov 2016	25 Apr 2019	05 Aug 2016	07 Sep 2016
Germany	04 Aug 2017	31 Jul 2019	27 Jul 2017	31 Jul 2019
UK	18 May 2018	07 Jun 2018	01 Aug 2016	07 Sep 2016
Greece	01 Sep 2016	20 Sep 2016	01 Sep 2016	29 Sep 2016
Nordics	16 Sep 2016	31 Jul 2019	04 Aug 2016	30 Nov 2016

HCP=healthcare professional

10.1.1 Healthcare professionals

A summary of HCP respondents’ medical specialties is presented for All HCP respondents in [Table 10-2](#).

Of the 169 participating HCPs, 147 HCP respondents (87%) were rheumatologists and 22 HCP respondents (13%) were rheumatology nurses. In each country, the proportion of HCP respondents who were rheumatologists ranged from 26 HCP respondents (100%) in Germany and 40 HCP respondents (100%) in Greece to 27 HCP respondents (68%) in the UK, and the HCP respondents who were rheumatology nurses ranged from 13 HCP respondents (33%) in the UK to 0 HCP respondents in Germany and Greece.

As described in Section 9.6, the actual sample size of HCP respondents per country was smaller than planned based on the earlier cessation of distribution of the Prescriber's Guide following PRAC feedback and in line with the agreed RMP v14.1.

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Table 10-2: Medical specialty by country (Question 0) (All HCP respondents)

Question Answer	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	Total N=169 n (%)
What is your medical specialty?						
Rheumatologist	34 (85)	26 (100)	27 (68)	40 (100)	20 (87)	147 (87)
Rheumatology nurse	6 (15)	0	13 (33)	0	3 (13)	22 (13)
Total	40 (100)	26 (100)	40 (100)	40 (100)	23 (100)	169 (100)

HCP=healthcare professional

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10.1.2 Patient respondents

A summary of patient disposition is presented for All patient respondents in [Table 10-3](#). A total of 48 patient respondents in France, 20 patient respondents in Germany, 61 patient respondents in the UK, 35 patient respondents in Greece, and 71 patient respondents in the Nordics agreed to the survey introductory text and met the age qualifications. For each country, the majority of patient respondents had completed an RMP survey previously. Of the patient respondents who received the Patient Alert Card, the majority or all read the Patient Alert Card in France (20 of 23), Germany (15 of 17), the UK (7 of 7), Greece (21 of 24), and the Nordics (5 of 5). A total of 20 patient respondents in France, 15 patient respondents in Germany, 6 patient respondents in the UK, 20 patient respondents in Greece, and 2 patient respondents in the Nordics met all entry criteria and successfully completed the survey.

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Table 10-3: Number of patient respondents approached, screened, eligible, and completed surveys by country (Question 0a, Question 0b, Question 2, Question 3, and Question 6) (All patient respondents)

Question Answer	France	Germany	UK	Greece	Nordics
	N=48	N=20	N=61	N=35	N=71
How old are you?					
Agreed to survey intro text and were a qualified age	48	19	61	33	71
Are you a qualified HCP, eg, doctor, nurse, pharmacist?					
Not a qualified HCP	47	19	56	26	67
Have you previously completed a survey regarding educational tools for CIMZIA® (certolizumab pegol), within the last 12 months?					
Not previously completed a RMP survey	44	17	8	24	2
Have you received the Patient Alert Card for CIMZIA® (certolizumab pegol) from your prescribing physician/HCP?					
Received the Patient Alert Card	23	17	7	21	5
Have you read the Patient Alert Card for CIMZIA® (certolizumab pegol)					
Read the Patient Alert Card	20	15	7	20	5
Qualified incompletes ^a	0	0	1	0	3
Completers	20	15	6	20	2

HCP=healthcare professional; RMP=Risk Minimization Plan

^a A small number of entrants to the online survey qualified to complete the full survey but did not go on to complete the survey. Also note that a small number of respondents left the survey between Question 1 and Question 4.

10.2 Descriptive data

10.2.1 Healthcare professionals

A summary of HCP respondents who previously completed a survey on Global Risk Minimization tools is presented for all screened HCP respondents in [Table 10-4](#). All screened HCP respondents include incomplete responders, screenouts, completers, and qualified survey dropouts, except from Germany, where all respondents were recruited from a list and prescreened.

The proportion of HCP respondents who had not previously completed a survey on Global Risk Minimization tools was high (97%), and ranged from 100% in Germany to 97% in France and the UK. Healthcare providers who indicated they had previously completed a survey on Global Risk Minimization tools were screened out.

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**Table 10-4: Previously completed a survey on Global Risk Minimization Tools (Question 1)
 (All screened HCP respondents)**

Question Answer	Country					
	France n=68 n (%)	Germany n=26 n (%)	UK n=74 n (%)	Greece n=53 n (%)	Nordics n=81 n (%)	Total n=276 n (%)
Have you previously completed a survey regarding Global Risk Minimization Plan tools for CIMZIA® (certolizumab pegol) in the last 12 months?						
Yes	2 (3)	0	2 (3)	4 (8)	1 (1)	7 (3)
No	66 (97)	26 (100)	72 (97)	49 (92)	80 (99)	267 (97)

HCP=healthcare professional

Note: All screened HCP respondents included incompletes, screenouts, completes, and qualified survey dropouts, except Germany, where all respondents were recruited from a list and prescreened.

A summary of HCP experience with CZP is presented for All HCP respondents in [Table 10-5](#).

All rheumatologists and rheumatology nurses had either prescribed CZP (142 HCP respondents [97%] and 2 HCP respondents [9%], respectively) or administered and/or monitored the use of CZP (5 HCP respondents [3%] and 20 HCP respondents [91%], respectively). Across countries, the number of HCP respondents who prescribed CZP previously ranged from 26 HCP respondents (100%) in Germany to 29 HCP respondents (73%) in the UK, and the proportion of HCP respondents who administered and/or monitored the use of CZP but have not prescribed CZP previously ranged from 11 HCP respondents (28%) in the UK to 0 HCP respondents in Germany.

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Table 10-5: Experience with CZP (Question 2) (All HCP respondents)

Question Answer	Specialty		Country					Total N=169 n (%)
	Rheumatologist N=147 n (%)	Rheumatology Nurse N=22 n (%)	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	
Please indicate which statement best describes your experience with CIMZIA® (certolizumab pegol):								
Prescribed CZP	142 (97)	2 (9)	31 (78)	26 (100)	29 (73)	39 (98)	19 (83)	144 (85)
Administered and/or monitored the use of CZP, but have not prescribed it	5 (3)	20 (91)	9 (23)	0	11 (28)	1 (3)	4 (17)	25 (15)
Never prescribed, administered nor monitored the use of CZP	0	0	0	0	0	0	0	0

CZP=CIMZIA® (certolizumab pegol); HCP=healthcare professional

10.2.2 Patient respondents

A summary of the age of patient respondents is presented for All patient respondents in [Table 10-6](#).

Overall, the mean age was similar for France (50.2 years), Germany (51.87 years), Greece (53.05 years), and the Nordics (56 years), and was lower in the UK (42.5 years). Patient respondents were most commonly in the 51-to-60-year age range (22 patient respondents [35%]) and the 41-to-50-year age range (17 patient respondents [27%]).

Table 10-6: Age of patient respondents who completed the survey (Question 0a) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 n (%)	UK N=6 n (%)	Greece N=20 n (%)	Nordics N=2 n (%)	Total N=63 n (%)
How old are you?						
18 to 30 years	1 (5)	1 (7)	2 (33)	0	0	4 (6)
31 to 40 years	4 (20)	0	1 (17)	3 (15)	0	8 (13)
41 to 50 years	5 (25)	5 (33)	2 (33)	4 (20)	1 (50)	17 (27)
51 to 60 years	7 (35)	7 (47)	0	8 (40)	0	22 (35)
61 to 70 years	2 (10)	2 (13)	0	4 (20)	1 (50)	9 (14)
>70 years	1 (5)	0	1 (17)	1 (5)	0	3 (5)
Mean	50.2	51.87	42.5	53.05	56	50.95

A summary of patient respondents who started CZP treatment in the past 6 months is presented for all patient respondents who answered Question 1a in [Table 10-7](#).

Four patient respondents (100%) in France, 15 patient respondents (100%) in Germany, 0 patient respondents in the UK, 20 patient respondents (100%) in Greece, and 1 patient respondent (100%) in the Nordics had CZP prescribed within the last 6 months.

Table 10-7: Prescription of CIMZIA® (certolizumab pegol) treatment within the last 6 months (Question 1a) (All patient respondents)

Question Answer	France N=4 n (%)	Germany N=15 n (%)	UK N=0 n (%)	Greece N=20 n (%)	Nordics N=1 n (%)	Total N=40 n (%)
Has CIMZIA® (certolizumab pegol) ever been prescribed for you in the last 6 months?						
Yes	4 (100)	15 (100)	0	20 (100)	1 (100)	40 (100)
No	0	0	0	0	0	0

Note: Responses were presented only for patient respondents who answered this question.

A summary of patient respondents who were prescribed treatments in the past 6 months is presented for all patient respondents who answered Question 1a New in [Table 10-8](#).

Sixteen patient respondents (100%) in France, 0 patient respondents in Germany, 6 patient respondents (100%) in the UK, 0 patient respondents in Greece, and 1 patient (100%) in the Nordics were prescribed CZP treatment within the last 6 months. One patient (6%) in France was prescribed etanercept within the last 6 months.

Table 10-8: Prescription of treatments within the last 6 months (Question 1a New) (All patient respondents)

Question Answer	France N=16 n (%)	Germany N=0 n (%)	UK N=6 n (%)	Greece N=0 n (%)	Nordics N=1 n (%)	Total N=23 n (%)
Have any of the following treatments ever been prescribed for you in the last 6 months?						
CIMZIA® (certolizumab pegol)	16 (100)	0	6 (100)	0	1 (100)	23 (100)
ENBREL® (etanercept)	1 (6)	0	0	0	0	1 (4)

Note: Responses were presented only for patient respondents who answered this question.

A summary of patient characteristics is presented for All patient respondents in [Table 10-9](#).

Per the criteria for study entry, all 63 patient respondents (Question 1a or Question 1a New) were currently receiving treatment with CZP. If the patient respondent was recruited through the HCP where it was known they were prescribed CZP, Question 1a was asked; if the patient respondent was recruited through other means, eg, through patient associations then Question 1a New was asked to ascertain that the patient was taking CZP. Overall, patient respondents have most commonly been receiving CZP treatment for 12 to 18 months (21 patient respondents [33%]) followed by <12 months (18 patient respondents [29%]) and 19 to 24 months (10 patient respondents [16%]). Across all countries, 42 patient respondents (67%) had been treated with an anti-TNF or another biologic agent before starting treatment with CZP and 20 patient respondents (32%) had not received previous anti-TNF or biologic treatment. In each individual country, the majority of patient respondents received anti-TNF or another biologic agent before starting treatment with CZP.

Table 10-9: Patient characteristics (Question 1b, Question 1c, and Question 1d) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 (%)	UK N=6 (%)	Greece N=20 (%)	Nordics N=2 (%)	Total N=63 (%)
Are you currently being treated with CIMZIA® (certolizumab pegol)?						
Yes	20 (100)	15 (100)	6 (100)	20 (100)	2 (100)	63 (100)
For how long have you been / were you treated with CIMZIA® (certolizumab pegol)?						
<12 months	6 (30)	4 (27)	2 (33)	6 (30)	0	18 (29)
12 to 18 months	3 (15)	4 (27)	2 (33)	12 (60)	0	21 (33)
19 to 24 months	2 (10)	5 (33)	0	2 (10)	1 (50)	10 (16)
25 to 36 months	2 (10)	2 (13)	1 (17)	0	0	5 (8)
37 to 48 months	2 (10)	0	0	0	1 (50)	3 (5)
>48 months	5 (25)	0	1 (17)	0	0	6 (10)
Have you been treated with an anti-TNF or another biologic agent before starting treatment with CIMZIA® (certolizumab pegol)?						
Yes	14 (70)	11 (73)	4 (67)	11 (55)	2 (100)	42 (67)
No	5 (25)	4 (27)	2 (33)	9 (45)	0	20 (32)
Don't know	1 (5)	0	0	0	0	1 (2)

TNF=tumor necrosis factor

10.3 Outcome data

10.3.1 Healthcare professionals

10.3.1.1 CZP educational materials receipt, awareness, access, and understanding

10.3.1.1.1 CZP Prescriber Guide

A summary of the proportion of HCP respondents who received the CZP Prescriber Guide is presented for All HCP respondents in [Table 10-10](#).

Overall, the majority of HCP respondents (69%) received the Prescriber Guide. The majority of HCP respondents in France (73%), Germany (100%), the UK (74%), and Greece (96%) received the CZP Prescriber guide, though receipt was lower in the Nordics (44%). In each country, the proportion of HCP respondents who received the CZP Prescriber Guide was above or within the EMA usage target of 35% to 60% ([Table 6-1](#)).

**Table 10-10: HCP respondents who received the Prescriber Guide (Question 3)
(All screened HCP respondents ^a)**

Question Answer	France N=62 n (%)	Germany N=26 n (%)	UK N=69 n (%)	Greece N=49 n (%)	Nordics N=73 n (%)	Total N=253 n (%)
Have you received the Prescriber Guide?						
Yes	45 (73)	26 (100)	51 (74)	47 (96)	32 (44)	175 (69)
No	17 (27)	0	18 (26)	2 (4)	41 (56)	78 (31)

HCP=healthcare practitioner

Note: Percentages were calculated based on the number of screened patient respondents. Patient respondents who answered “no” to Question 3 (Have you received the Patient Alert Card for CIMZIA® (certolizumab pegol) from your prescribing physician/HCP?) were screened out and were not asked further questions.

^a All screened HCP respondents included (incompletes, screenouts, completes and qualified survey dropouts except Germany where all respondents were recruited from list and prescreened).

A summary of the proportions of HCP respondents who read the CZP Prescriber Guide is presented for All HCP respondents in [Table 10-11](#).

The majority of HCP respondents in France (91%), Germany (100%), the UK (84%), Greece (96%), and the Nordics (84%) read the CZP Prescriber guide. The proportion of HCP respondents in each country who read the Prescriber Guide was above the EMA usage target of 35% to 60% ([Table 6-1](#)).

**Table 10-11: HCP respondents who read the Prescriber Guide (Question 4)
(All HCP respondents ^a)**

Question Answer	France N=45 n (%)	Germany N=26 n (%)	UK N=51 n (%)	Greece N=47 n (%)	Nordics N=32 n (%)	Total N=175 n (%)
Have you read the Prescriber Guide?						
Yes	41 (91)	26 (100)	43 (84)	45 (96)	27 (84)	156 (89)
No	4 (9)	0	8 (16)	2 (4)	5 (16)	19 (11)

CZP=CIMZIA® (certolizumab pegol); HCP=healthcare practitioner

^a All screened HCP respondents included (incompletes, screenouts, completes and qualified survey dropouts except Germany where all respondents were recruited from a list and prescreened).

A summary of HCP understanding of the Prescriber Guide is presented for All HCP respondents in [Table 10-12](#).

Overall, the CZP Prescriber Guide was well understood with 164 HCP respondents (97%) understanding all information in the CZP Prescriber Guide, and proportions were similar in rheumatologists (143 HCP respondents [97%]) and rheumatology nurses (21 HCP respondents [95%]). The proportions of HCP respondents who understood all information in the CZP Prescriber Guide were high and similar between countries ($\geq 95\%$ in each country).

Overall, almost all HCP respondents were confident in their understanding of the potential risks of CZP treatment with answers of somewhat confident (46 HCP respondents [27%]), very confident (89 HCP respondents [53%]), or extremely confident (32 HCP respondents [19%]). More rheumatologists were extremely confident compared with rheumatology nurses (31 HCP respondents [21%] vs 1 HCP [5%], respectively) and very confident (81 HCP respondents [55%] vs 8 HCP respondents [36%], respectively). Only 2 HCP respondents (1%) (both rheumatologists) answered not very confident. No notable differences in HCP confidence were observed in individual countries compared with overall trends.

Overall, the majority of HCP respondents (152 [90%]) did not have unanswered questions concerning the usage of CZP after reading the CZP Prescriber Guide, with high proportions of rheumatologists (135 HCP respondents [92%]) and rheumatology nurses (17 HCP respondents [77%]) who had no unanswered questions. In individual countries, the proportions of HCP respondents who had no unanswered questions concerning the usage of CZP after reading the CZP Prescriber Guide ranged from 26 HCP respondents (100%) in Germany and 23 HCP respondents (100%) in the Nordics to 32 HCP respondents (80%) in the UK.

Table 10-12: Understanding the CIMZIA® Prescriber Guide (Question 5a, Question 6, and Question 7) (All HCP respondents)

Question Answer	Specialty		Country					
	Rheumatologist N=147 n (%)	Rheumatology Nurse N=22 n (%)	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	Total N=169 n (%)
Did you understand all of the information provided in the Prescriber Guide?								
Yes	143 (97)	21 (95)	38 (95)	26 (100)	38 (95)	40 (100)	22 (96)	164 (97)
No	4 (3)	1 (5)	2 (5)	0	2 (5)	0	1 (4)	4 (3)
How confident do you feel that you understand the identified and potential risks of CIMZIA® (certolizumab pegol) treatment?								
Not at all confident (1)	0	0	0	0	0	0	0	0
Not very confident (2)	2 (1)	0	1 (3)	0	1 (3)	0	0	2 (1)
Somewhat confident (3)	33 (22)	13 (59)	20 (50)	2 (8)	12 (30)	2 (5)	10 (43)	46 (27)
Very confident (4)	81 (55)	8 (36)	16 (40)	16 (62)	23 (58)	21 (53)	13 (57)	89 (53)
Extremely confident (5)	31 (21)	1 (5)	3 (8)	8 (31)	4 (10)	17 (43)	0	32 (19)
After reading the Prescriber Guide, did you have any unanswered questions concerning the usage of CIMZIA® (certolizumab pegol)?								
Yes	12 (8)	5 (23)	4 (10)	0	8 (20)	5 (13)	0	17 (10)
No	135 (92)	17 (77)	36 (90)	26 (100)	32 (80)	35 (88)	23 (100)	152 (90)

HCP=healthcare provider

10.3.1.1.2 Patient Alert Card

A summary of the HCP respondents who received the Patient Alert Card is presented for All HCP respondents in [Table 10-13](#).

Overall, 113 HCP respondents (67%) indicated they received the Patient Alert Card, 43 HCP respondents (25%) answered they did not recall, and 13 HCP respondents (8%) indicated they had not received the Patient Alert Card. The proportions of rheumatologists and rheumatology nurses were similar for those who indicated they received the Patient Alert Card (99 HCP respondents [67%] and 14 HCP respondents [64%], respectively), those who indicated they did not recall (37 HCP respondents [25%] and 6 HCP respondents [27%], respectively), and those who indicated they had not received the Patient Alert Card (11 HCP respondents [7%] and 2 HCP respondents [9%], respectively).

In individual countries, the proportions of HCP respondents who indicated they received the Patient Alert Card were higher in Germany (25 HCP respondents [96%]) and Greece (34 HCP respondents [85%]) compared with France (18 HCP respondents [45%]) and the UK (22 HCP respondents [55%]). In France and the UK, of the HCP respondents who did not answer 'Yes,' almost all (19 HCP respondents [48%] and 15 HCP respondents [38%], respectively) indicated they did not remember if they had received the Patient Alert Card.

Table 10-13: HCP receipt of the Patient Alert Card (Question 10) (All HCP respondents)

Question Answer	Specialty		Country					
	Rheumatologist N=147 n (%)	Rheumatology Nurse N=22 n (%)	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	Total N=169 n (%)
Have you received the Patient Alert Card?								
Yes	99 (67)	14 (64)	18 (45)	25 (96)	22 (55)	34 (85)	14 (61)	113 (67)
No	11 (7)	2 (9)	3 (8)	0	3 (8)	4 (10)	3 (13)	13 (8)
Do not know/cannot recall	37 (25)	6 (27)	19 (48)	1 (4)	15 (38)	2 (5)	6 (26)	43 (25)

HCP=healthcare professional

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A summary of the HCP use of the Patient Alert Card is presented for All HCP respondents in [Table 10-14](#).

Overall, the proportion of HCP respondents who read the Patient Alert Card was high (107 HCP respondents [95%]), including rheumatologists (93 HCP respondents [94%]) and rheumatology nurses (14 HCP respondents [100%]). By individual country, the proportions of HCP respondents who read the Patient Alert Card were also high and ranged from 25 HCP respondents (100%) and 34 HCP respondents (100%) in Germany and Greece, respectively, to 11 HCP respondents (79%) in the Nordics.

Overall, the proportion of HCP respondents who provided the Patient Alert Card to patient respondents for whom they had prescribed administered and/or monitored CZP was high (94 HCP respondents [83%]), including rheumatologists (81 HCP respondents [82%]) and rheumatology nurses (13 HCP respondents [93%]). By individual country, the proportions of HCP respondents who provided the Patient Alert Card to patient respondents for whom they had prescribed administered and/or monitored CZP ranged from 24 HCP respondents (96%) in Germany to 8 HCP respondents (57%) in the Nordics.

The majority of HCP respondents (74 HCP respondents [65%]) provided guidance on how to use the Patient Alert Card to patient respondents for whom they had prescribed, administered, and/or monitored the use of CZP, with a lower proportion of rheumatologists providing guidance compared with rheumatology nurses (61 HCP respondents [62%] vs 13 HCP respondents [93%], respectively). By individual country, the proportions of HCP respondents who provided guidance on how to use the Patient Alert Card to patient respondents for whom they had prescribed, administered, and/or monitored the use of CZP ranged from 15 HCP respondents (83%) in France to 5 HCP respondents (36%) in the Nordics.

**Table 10-14: HCP use of the Patient Alert Card (Question 11, Question 12, and Question 13)
 (All HCP respondents ^a)**

Question Answer	Specialty		Country					
	Rheumatologist N=99 n (%)	Rheumatology Nurse N=14 n (%)	France N=18 n (%)	Germany N=25 n (%)	UK N=22 n (%)	Greece N=34 n (%)	Nordics N=14 n (%)	Total N=113 n (%)
Have you read the Patient Alert Card?								
Yes	93 (94)	14 (100)	16 (89)	25 (100)	21 (95)	34 (100)	11 (79)	107 (95)
No	6 (6)	0	2 (11)	0	1 (5)	0	3 (21)	6 (5)
Have you provided the Patient Alert Card to those patients for whom you have prescribed, administered and/or monitored the use of CIMZIA[®] (certolizumab pegol)?								
Yes	81 (82)	13 (93)	16 (89)	24 (96)	20 (91)	26 (76)	8 (57)	94 (83)
No	18 (18)	1 (7)	2 (11)	1 (4)	2 (9)	8 (24)	6 (43)	19 (17)
Have you ever provided guidance on how to use the Patient Alert Card to patients for whom you have prescribed, administered and/or monitored the use of CIMZIA[®] (certolizumab pegol)?								
Yes	61 (62)	13 (93)	15 (83)	12 (48)	17 (77)	25 (74)	5 (36)	74 (65)
No	38 (38)	1 (7)	3 (17)	13 (52)	5 (23)	9 (26)	9 (64)	39 (35)

HCP=healthcare provider

^a Only the responses of HCPs who answered 'Yes' to Question 10 are presented.

A summary of Patient Alert Card utility responses is presented for All HCPs respondents in [Table 10-15](#).

Overall, the majority of HCP respondents thought that the Patient Alert Card was extremely useful (18 HCP respondents [11%]) or very useful (81 HCP respondents [48%]), and 55 HCP respondents (33%) found the Patient Alert Card somewhat useful. The majority of rheumatologists and rheumatology nurses found the Patient Alert Card extremely useful, very useful, or somewhat useful and in similar proportions to the overall results. The answers 'Very Useful' and 'Somewhat Useful' were most frequently chosen by HCP respondents in France (16 HCP respondents [40%] each), the answers 'Very Useful' and 'Somewhat Useful' were most frequently chosen by HCP respondents in the UK (18 HCP respondents [45%] each), 'Very Useful' was chosen most frequently by HCP respondents in Germany (16 HCP respondents [62%]), and 'Very Useful' was most frequently chosen by HCP respondents in Greece (17 HCP respondents [43%]) and the Nordics (14 HCP respondents [61%]).

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Table 10-15: Patient Alert Card utility (Question 14) (All HCP respondents)

Question Answer	Specialty		Country					
	Rheumatologist N=147 n (%)	Rheumatology Nurse N=22 n (%)	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	Total N=169 n (%)
How useful do you think the Patient Alert Card is for patients being treated with CIMZIA® (certolizumab pegol)?								
Not at all useful (1)	2 (1)	1 (5)	0	0	1 (3)	2 (5)	0	3 (2)
Not very useful (2)	11 (7)	1 (5)	6 (15)	1 (4)	1 (3)	1 (3)	3 (13)	12 (7)
Somewhat useful (3)	48 (33)	7 (32)	16 (40)	5 (19)	18 (45)	11 (28)	5 (22)	55 (33)
Very useful (4)	69 (47)	12 (55)	16 (40)	16 (62)	18 (45)	17 (43)	14 (61)	81 (48)
Extremely useful (5)	17 (12)	1 (5)	2 (5)	4 (15)	2 (5)	9 (23)	1 (4)	18 (11)

HCP=healthcare provider

10.3.1.2 Recall of important CZP safety information

A summary of the correct responses for HCP identification of the serious risks associated with CZP is presented for All HCP respondents in [Table 10-16](#).

In general, the majority of HCP respondents were able to correctly identify which risks were and were not associated with CZP. The most common ($\geq 80\%$) correctly identified risks that were associated with CZP were serious bacterial infection (149 HCP respondents [88%]), allergic reactions (147 HCP respondents [88%]), opportunistic infections (eg, histoplasmosis, nocardia, and candidiasis) (142 HCP respondents [84%]), tuberculosis (TB) (142 HCP respondents [84%]), bacterial sepsis (141 HCP respondents [83%]), and hepatitis B virus (HBV) reactivation (135 HCP respondents [80%]). Generally, the proportion of HCP respondents that correctly identified risks that were not associated with CZP was lower than the proportion of HCP respondents that correctly identified risks associated with CZP, and no risk category that was not associated with CZP was chosen correctly by $>80\%$ of HCP respondents. While country-to-country variability was observed in the proportions of HCP respondents who correctly identified serious risks either associated or not associated with CZP, in general the proportions of correct responses by country were similar to the proportions of responses in All HCP respondents.

**Table 10-16: Identification of serious risks associated with CIMZIA® (correct responses) (Question 17)
(All HCP respondents)**

Correct Answer Serious risk	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	Total N=169 n (%)
Yes						
Serious bacterial and viral infection	38 (95)	24 (92)	34 (85)	33 (83)	20 (87)	149 (88)
Allergic reactions	35 (88)	24 (92)	36 (90)	32 (80)	20 (87)	147 (88)
A lupus-like syndrome	27 (68)	6 (23)	29 (73)	31 (78)	13 (57)	106 (63)
Hepatobiliary events	24 (60)	21 (81)	15 (38)	14 (35)	8 (35)	82 (49)
Bacterial sepsis	36 (90)	22 (85)	32 (80)	32 (80)	19 (83)	141 (83)
Hepatitis B virus reactivation	31 (78)	26 (100)	26 (65)	32 (80)	20 (87)	135 (80)
Opportunistic infections (eg, histoplasmosis, nocardia, and candidiasis)	33 (83)	25 (96)	33 (83)	33 (83)	18 (78)	142 (84)
Immune disorders such as sarcoidosis	23 (58)	19 (73)	15 (38)	19 (48)	6 (26)	82 (49)
Tuberculosis	35 (88)	26 (100)	29 (73)	32 (80)	20 (87)	142 (84)
Malignancies (including lymphoma, leukemia, Merkel cell carcinoma, and melanoma)	27 (68)	18 (69)	27 (68)	19 (48)	15 (65)	106 (63)
New or worsening psoriasis	29 (73)	12 (46)	22 (55)	32 (80)	8 (35)	103 (61)
Heart failure	23 (58)	20 (77)	19 (48)	28 (70)	13 (57)	103 (61)
No						
Nose bleeds	20 (50)	25 (96)	21 (53)	21 (53)	12 (52)	99 (59)
Cerebrovascular accident	27 (68)	22 (85)	25 (63)	23 (58)	13 (57)	110 (65)
Decreased bone density	28 (70)	20 (77)	27 (68)	29 (73)	19 (83)	123 (73)

**Table 10-16: Identification of serious risks associated with CIMZIA® (correct responses) (Question 17)
 (All HCP respondents)**

Correct Answer Serious risk	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	Total N=169 n (%)
Intestinal bleeding	25 (63)	19 (73)	25 (63)	24 (60)	11 (48)	104 (62)
Intractable nausea and vomiting	22 (57)	19 (73)	25 (63)	16 (40)	14 (61)	96 (57)
Memory loss	27 (68)	24 (92)	27 (68)	24 (60)	14 (61)	116 (69)
Hypertension	22 (55)	4 (15)	24 (60)	21 (53)	12 (52)	83 (49)
Migraine headaches	18 (45)	23 (88)	15 (38)	10 (25)	11 (48)	77 (46)

HCP=healthcare practitioner

Note: Incorrect responses and responses of “I don’t know” are not included in this table.

A summary of the correct responses to statements regarding the use of CZP is presented for All HCP respondents in [Table 10-17](#).

Overall, the proportions of HCP respondents who correctly answered questions regarding the use of CZP with 'True' was high and ranged from 162 HCP respondents (96%) for the question 'CIMZIA[®] (certolizumab pegol) should be discontinued if a patient develops a serious infection or sepsis' to 144 HCP respondents (85%) answering 'True' for the question 'Patients should be monitored for signs and symptoms of chronic heart failure.' The proportions of HCP respondents who correctly answered 'True' to statements regarding CZP were similar by country to the overall proportions and none of the by-country question results differed by $\geq 8\%$ compared with All HCP respondents.

Overall, the proportions of HCP respondents who correctly answered questions regarding the use of CZP as 'False' ranged from 121 HCP respondents (72%) for the question 'Live or attenuated vaccines may be given concurrently with CIMZIA[®] (certolizumab pegol)' to 56 HCP respondents (33%) answering 'False' for the question 'CIMZIA[®] (certolizumab pegol) therapy may be continued if a patient develops HBV reactivation, provided an effective antiviral therapy with appropriate supportive treatment has been initiated.'

Table 10-17: Please indicate if the following statements regarding the use of CIMZIA (certolizumab pegol) are True or False (correct answers) (Question 18) (All HCP respondents)

Question Answer	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	Total N=169 n (%)
True						
CIMZIA® (certolizumab pegol) should be discontinued if a patient develops a serious infection or sepsis	38 (95)	26 (100)	37 (93)	39 (98)	22 (96)	162 (96)
Exercise caution when considering the use of CIMZIA® (certolizumab pegol) in patients with a history of recurrent infection	37 (93)	24 (92)	37 (93)	38 (95)	21 (91)	157 (93)
Patients should be instructed to seek medical advice in the following circumstances: 1. family or other contact history of persons with active TB, 2. change in level of PPD/IGRA, 3. recent foreign travel in endemic TB countries	35 (88)	24 (92)	37 (93)	38 (95)	21 (91)	155 (92)
Patients should be monitored for signs and symptoms of chronic heart failure	31 (78)	24 (92)	35 (88)	39 (98)	15 (65)	144 (85)
CIMZIA® (certolizumab pegol) therapy should be stopped immediately if severe hypersensitivity reactions occur	39 (98)	22 (85)	36 (90)	38 (95)	22 (96)	157 (93)
False						
Live or attenuated vaccines may be given concurrently with CIMZIA® (certolizumab pegol)	33 (83)	7 (27)	32 (80)	28 (70)	21 (91)	121 (72)

Table 10-17: Please indicate if the following statements regarding the use of CIMZIA (certolizumab pegol) are True or False (correct answers) (Question 18) (All HCP respondents)

Question Answer	France N=40 n (%)	Germany N=26 n (%)	UK N=40 n (%)	Greece N=40 n (%)	Nordics N=23 n (%)	Total N=169 n (%)
Development of malignancies during CIMZIA® (certolizumab pegol) treatment is unrelated to the therapy and concerning patients about such a risk is unnecessary	37 (93)	4 (15)	19 (48)	22 (55)	15 (65)	97 (57)
CIMZIA® (certolizumab pegol) therapy may be continued if a patient develops HBV reactivation, provided an effective antiviral therapy with appropriate supportive treatment has been initiated	15 (38)	14 (54)	11 (28)	10 (25)	6 (26)	56 (33)

HBV=hepatitis B virus; HCP=healthcare provider; IGRA=interferon-gamma release assay; PPD=purified protein derivative; TB=tuberculosis

10.3.2 Patient respondents

10.3.2.1 CZP educational materials receipt, awareness, access, and understanding

A summary of the patient respondents who received the CZP Patient Alert Card is presented for All patient respondents in [Table 10-18](#).

In total, 73% of patient respondents received the Patient Alert Card, including 52% of patient respondents in France, 100% of patient respondents in Germany, 75% of patient respondents in the UK, 88% of patient respondents in Greece, and 100% of patient respondents in the Nordics and was above the EMA usage target of 35% to 50% in each country ([Table 6-1](#)).

Table 10-18: Patient respondents who received the CZP Patient Alert Card (Question 3) (All patient respondents)

Question Answer	France N=44 n (%)	Germany N=17 n (%)	UK N=8 n (%)	Greece N=24 n (%)	Nordics N=2 n (%)	Total N=95 n (%)
Have you received the Patient Alert Card for CIMZIA® (certolizumab pegol) from your prescribing physician/HCP?						
Yes	23 (52)	17 (100)	6 (75)	21 (88)	2 (100)	69 (73)
No	21 (48)	0	2 (25)	3 (13)	0	25 (27)

CZP=certolizumab pegol (CIMZIA®); HCP=healthcare practitioner

Note: Percentages were calculated based on the number of screened patient respondents. Patient respondents who answered “no” to Question 3 (Have you received the Patient Alert Card for CIMZIA® (certolizumab pegol) from your prescribing physician/HCP?) were screened out and were not asked further questions.

A summary of when patient respondents received the Patient Alert Card is presented for All patient respondents in [Table 10-19](#).

All but 1 patient received his/her patient alert card when treatment started (47 patient respondents [75%]) or before treatment started (15 patient respondents [24%]). In each country, patient respondents more commonly received their Patient Alert Card when treatment started, except for the UK, where patient respondents more commonly received their Patient Alert Card before treatment started.

Table 10-19: Timing of the CZP Patient Alert Card receipt (Question 4) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 n (%)	UK N=6 n (%)	Greece N=20 n (%)	Nordics N=2 n (%)	Total N=63 n (%)
When did you receive the Patient Alert Card for CIMZIA® (certolizumab pegol)?						
Before treatment start	6 (30)	3 (20)	3 (50)	3 (15)	0	15 (24)
When treatment started	14 (70)	12 (80)	2 (33)	17 (85)	2 (100)	47 (75)
Can't recall or do not know	0	0	1 (17)	0	0	1 (2)

CZP=certolizumab pegol (CIMZIA®)

A summary of patient respondents whose physician explained the reason they received the Patient Alert Card is presented for All patient respondents in [Table 10-20](#).

The majority of patient respondents indicated that their physician explained why they received the Patient Alert Card for CZP (50 patient respondents [79%]), and the proportion ranged from 14 patient respondents (93%) in Germany to 3 patient respondents (50%) and 1 patient (50%) in the UK and the Nordics, respectively.

Table 10-20: Physician explanation of the CZP Patient Alert Card receipt (Question 5a) (All patient respondents)

Question Answer	France n=20 (%)	Germany n=15 (%)	UK n=6 (%)	Greece n=20 (%)	Nordics n=2 (%)	Total n=63 (%)
Did your physician explain why you received the Patient Alert Card for CIMZIA® (certolizumab pegol)?						
Yes	16 (80)	14 (93)	3 (50)	16 (80)	1 (50)	50 (79)
No	4 (20)	1 (7)	3 (50)	4 (20)	1 (50)	13 (21)

CZP=certolizumab pegol (CIMZIA®)

A summary of the patient respondents who read the CZP Patient Alert Card is presented for All patient respondents in [Table 10-21](#).

Overall, the proportion of patient respondents who read the CZP Patient was high (91%) and ranged from 100% in the UK and the Nordics to 88% in Germany, which was above the EMA target of 35% to 50% ([Table 6-1](#)).

Table 10-21: Patient respondents who read the CZP Patient Alert Card (Question 6) (All patient respondents)

Question Answer	France N=23 n (%)	Germany N=17 n (%)	UK N=6 n (%)	Greece N=21 n (%)	Nordics N=2 n (%)	Total N=69 n (%)
Have you read the Patient Alert Card for CIMZIA® (certolizumab pegol)?						
Yes	20 (87)	15 (88)	6 (100)	20 (95)	2 (100)	63 (91)
No	3 (13)	2 (12)	0	1 (5)	0	6 (9)

CZP=certolizumab pegol

A summary of patient understanding of the Patient Alert Card is presented for All patient respondents in [Table 10-22](#).

The proportion of patient respondents who indicated they understood all the information displayed in the Patient Alert Card for CZP was high (61 patient respondents [97%]), and ranged from 2 patient respondents (100%) in the Nordics to 14 patient respondents (93%) in Germany. The majority of patient respondents (44 patient respondents [70%]) indicated that the Patient Alert Card increased their knowledge and confidence with their CZP treatment, which ranged from 5 patient respondents (83%) in the UK to 11 patient respondents (55%) in France.

Table 10-22: Patient understanding of the Patient Alert Card (Question 7a and Question 8a) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 n (%)	UK N=6 n (%)	Greece N=20 n (%)	Nordics N=2 n (%)	Total N=63 n (%)
Did you understand all the information displayed on the Patient Alert Card for CIMZIA® (certolizumab pegol)?						
Yes	19 (95)	14 (93)	6 (100)	20 (100)	2 (100)	61 (97)
No	1 (5)	1 (7)	0	0	0	2 (3)
Has the Patient Alert Card for CIMZIA® (certolizumab pegol) increased your knowledge and confidence with your treatment with CIMZIA®?						
Yes	11 (55)	11 (73)	5 (83)	15 (75)	2 (100)	44 (70)
No	9 (45)	4 (27)	1 (17)	5 (25)	0	19 (30)

A summary of the patient respondents who discussed the Patient Alert Card when visiting a HCP is presented for All patient respondents in [Table 10-23](#). A total of 25 patient respondents (40%) indicated they discussed the Patient Alert Card when visiting an HCP, and ranged from 4 patient respondents (67%) in the UK to 3 patient respondents (20%) in Germany. The proportion of patient respondents who indicated that the information/advice on the Patient Alert Card prompted them to seek medical advice concerning potential side effect(s) of their CZP treatment

was 11 patient respondents (17%), with only Greece (6 patient respondents [30%]) and France 2 patient respondents [10%]) having >1 patient respondent do so.

Table 10-23: Discussion of the Patient Alert Card for CIMZIA® (certolizumab pegol) when visiting a Health Care Professional (Question 9 and Question 10) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 n (%)	UK N=6 n (%)	Greece N=20 n (%)	Nordics N=2 n (%)	Total N=63 n (%)
Have you ever shown and discussed the content in the Patient Alert Card for CIMZIA® (certolizumab pegol) when visiting a Health Care Professional?						
Yes	9 (45)	3 (20)	4 (67)	8 (40)	1 (50)	25 (40)
No	11 (55)	12 (80)	2 (33)	12 (60)	1 (50)	38 (60)
Has the information/advice on the Patient Alert Card prompted you to seek medical advice concerning potential side-effect(s) of your CIMZIA® (certolizumab pegol) treatment?						
Yes	2 (10)	1 (7)	1 (17)	6 (30)	1 (50)	11 (17)
No	18 (90)	14 (93)	5 (83)	14 (70)	1 (50)	52 (83)

A summary of patient respondents who kept up-to-date records of specific tests and/or potential treatments directly related to CZP treatment is presented for All patient respondents in [Table 10-24](#).

Approximately half of the patient respondents (33 patient respondents [52%]) indicated they kept an up-to-date record of the dates of specific tests and/or potential treatments (directly related to your treatment with CZP, and ranged from 12 patient respondents (80%) in Germany to 0 patient respondents in the Nordics.

Table 10-24: Have you kept an up-to-date record of the dates of specific tests and/or potential treatments (directly related to your treatment with CIMZIA® (Question 11) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 n (%)	UK N=6 n (%)	Greece N=20 n (%)	Nordics N=2 n (%)	Total N=63 n (%)
Have you kept an up-to-date record of the dates of specific tests and/or potential treatments (directly related to your treatment with CIMZIA®)?						
Yes	7 (35)	12 (80)	2 (33)	12 (60)	0	33 (52)
No	13 (65)	3 (20)	4 (67)	8 (40)	2 (100)	30 (48)

A summary of patient respondents who carried the Patient Alert Card with them at all times is presented for All patient respondents in [Table 10-25](#).

The majority of patient respondents (48 patient respondents [76%]) indicated that they carried the Patient Alert Card for CZP at all times and proportions by country ranged from 17 patient respondents (85%) in France to 9 patient respondents (45%) in Greece.

Table 10-25: Do you carry your Patient Alert Card for CIMZIA® (certolizumab pegol) with you at all times (Question 12) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 n (%)	UK N=6 n (%)	Greece N=20 n (%)	Nordics N=2 n (%)	Total N=63 n (%)
Do you carry your Patient Alert Card for CIMZIA® (certolizumab pegol) with you at all times?						
Yes	17 (85)	12 (80)	5 (83)	9 (45)	1 (50)	48 (76)
No	3 (15)	3 (20)	1 (17)	11 (55)	1 (50)	19 (30)

A summary of the patient respondents who indicated the Patient Alert Card for CZP informed them about what to do in case of specific events such as infections is presented in [Table 10-26](#).

The majority of patient respondents (44 patient respondents [70%]) indicated that the Patient Alert Card for CZP informed them about what to do in case of specific events such as infections, and proportions of patient respondents by country ranged from 20 patient respondents (100%) in Greece to 1 patient (50%) in the Nordics.

Table 10-26: Did your Patient Alert Card for CIMZIA® (certolizumab pegol) inform you on what to do in case of specific events such as infections? (Question 15) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 n (%)	UK N=6 n (%)	Greece N=20 n (%)	Nordics N=2 n (%)	Total N=63 n (%)
Did your Patient Alert Card for CIMZIA® (certolizumab pegol) inform you on what to do in case of specific events such as infections?						
Yes	13 (65)	9 (60)	5 (83)	20 (100)	1 (50)	44 (70)
No	1 (5)	2 (13)	1 (17)	0	1 (50)	5 (8)
I don't know	6 (30)	4 (27)	0	0	0	10 (16)

A summary of how helpful patient respondents thought the Patient Alert Card for CZP was is presented in [Table 10-27](#).

All patient respondents found the Patient Alert Card to be somewhat helpful (30 patient respondents [48%]), very helpful (26 patient respondents [41%]), or extremely helpful (7 patient respondents [11%]). No patient respondents found the Patient Alert Card to be not at all helpful or not very helpful. The answer 'Very helpful' was chosen most frequently by patient respondents in France (12 patient respondents [60%]) and Germany (6 patient respondents [40%]), the answer 'somewhat helpful' was most frequently chosen by patient

respondents in Greece (13 patient respondents [65%]) and the Nordics (2 patient respondents [100%]).

Table 10-27: Overall helpfulness of the Patient Alert Card for CZP (Question 16a) (All patient respondents)

Question Answer	France N=20 n (%)	Germany N=15 n (%)	UK N=6 n (%)	Greece N=20 n (%)	Nordics N=2 n (%)	Total N=63 n (%)
Overall, how helpful do you think the Patient Alert Card for CIMZIA® (certolizumab pegol) is?						
Not at all helpful	0	0	0	0	0	0
Not very helpful	0	0	0	0	0	0
Somewhat helpful	6 (30)	5 (33)	4 (67)	13 (65)	2 (100)	30 (48)
Very helpful	12 (60)	6 (40)	2 (33)	6 (30)	0	26 (41)
Extremely Helpful	2 (10)	4 (27)	0	1 (5)	0	7 (11)

CZP=certolizumab pegol (CIMZIA®)

10.3.2.2 Patient recall of important CZP safety information

A summary of the correct responses from patient identification of important CZP information is presented for All patient respondents in [Table 10-28](#).

The majority of patient respondents were able to correctly respond to each statement about CZP (range: 61 patient respondents [97%] to 41 patient respondents [65%]). The most common correctly identified statements were ‘You have to contact your doctor in case of persistent fever or infection’ (response of ‘True’) (61 patient respondents [97%]), ‘You should immediately contact your doctor and stop using CIMZIA® (certolizumab pegol) if you experience symptoms that could be due to an allergic reaction such as chest tightness, wheezing, dizziness, swelling or rash’ (response of ‘True’) (58 patient respondents [92%]), and ‘CIMZIA® (certolizumab pegol) should be stored at room temperature’ (response of ‘False’) (54 patient respondents [86%]).

While country-to-country variability was observed in the proportions of patient respondents who correctly identified statements related to CZP safety information, no noticeable trends were observed in the proportions of correct responses by country compared with the proportions of responses in All patient respondents.

Table 10-28: Please indicate if the following statements about CIMZIA® (certolizumab pegol) are True or False (correct answers) (Question 14) (All patient respondents)

Correct Answer Question	France n=20 (%)	Germany n=15 (%)	UK n=6 (%)	Greece n=20 (%)	Nordics n=2 (%)	Total n=63 (%)
True						
You should tell your doctor if you experience symptoms like shortness of breath or swelling of the feet while treated with CIMZIA® (certolizumab pegol)	14 (70)	13 (87)	5 (83)	19 (95)	2 (100)	53 (84)
You should inform your doctors if you are receiving anti-coagulant therapy or if you have a clotting test performed	10 (50)	13 (87)	5 (83)	13 (65)	0	41 (65)
You have to contact your doctor in case of persistent fever or infection	19 (95)	15 (100)	6 (100)	20 (100)	1 (50)	61 (97)
You should tell your doctor if you have ever had tuberculosis, or if you have been in close contact (example: living together) with someone who has had tuberculosis, or if you have visited / are living in a country (region) with a high prevalence of tuberculosis	12 (60)	14 (93)	6 (100)	20 (100)	1 (50)	53 (84)
You should immediately contact your doctor and stop using CIMZIA® (certolizumab pegol) if you experience symptoms that could be due to an allergic reaction such as chest tightness, wheezing, dizziness, swelling or rash	17 (85)	15 (100)	6 (100)	19 (95)	1 (50)	58 (92)
False						
CIMZIA® (certolizumab pegol) should be stored at room temperature	18 (90)	13 (87)	6 (100)	15 (75)	2 (100)	54 (86)

Note: Incorrect responses and responses of "I don't know" are not included in this table.

A summary of tests performed upon initiation of CZP treatment is presented for All patient respondents in [Table 10-29](#).

The majority of patient respondents (48 patient respondents [76%]) reported they were tested via blood test for hepatitis B virus infection prior to starting CZP treatment, and the proportion who reported they were tested ranged from 14 patient respondents (93%) in Germany to 1 patient respondent (50%) in the Nordics.

The majority of patient respondents (54 patient respondents [86%]) reported they were tested for potential TB infection prior to starting CZP treatment, and the proportion who reported they were tested ranged from 20 patient respondents (100%) and 6 patient respondents (100%) in Greece and the UK, respectively, to 1 patient (50%) in the Nordics. The most common TB tests reported by patient respondents were blood tests (28 patient respondents [52%]) and skin tests (25 patient respondents [46%]).

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Table 10-29: Tests performed upon initiation of CIMZIA® treatment (Question 13a, Question 13b, and Question 13c)

Question Answer	France	Germany	UK	Greece	Nordics	Total
Were you tested (by a blood test) for Hepatitis B infection before you started treatment with CIMZIA® (certolizumab pegol)?						
n	20	15	6	20	2	63
Yes, n (%)	12 (60)	14 (93)	4 (67)	17 (85)	1 (50)	48 (76)
No, n (%)	3 (15)	0	0	3 (15)	0	6 (10)
I don't know, n (%)	5 (25)	1 (7)	2 (33)	0	1 (50)	9 (14)
Did your doctor test you for potential tuberculosis infection before you started treatment with CIMZIA® (certolizumab pegol)?						
n	20	15	6	20	2	63
Yes, n (%)	14 (70)	13 (87)	6 (100)	20 (100)	1 (50)	54 (86)
No, n (%)	2 (10)	0	0	0	1 (50)	3 (5)
I don't know, n (%)	4 (20)	2 (13)	0	0	0	6 (10)
What specific test was performed for potential tuberculosis infection?						
n	14	13	6	20	1	54
Skin test, n (%)	1 (7)	4 (31)	0	20 (100)	0	25 (46)
Blood test, n (%)	10 (71)	10 (77)	5 (83)	2 (10)	1 (100)	28 (52)
Other test, n (%)	5 (36)	0	1 (17)	1 (5)	0	7 (13)
I cannot recall/I don't know, n (%)	2 (14)	3 (23)	1 (17)	0	0	6 (11)

10.4 Main results

10.4.1 Healthcare professionals

No statistical analyses were performed for this study, data were analyzed descriptively.

10.4.2 Patient respondents

No statistical analyses were performed for this study, data were analyzed descriptively.

10.5 Other analyses

Not applicable.

10.6 Adverse events/adverse reactions

Adverse events were collected as described in Section 11 of the protocol. One patient in France reported an AE of skin whitening that occurred at the injection spot. No other AEs were reported.

11 DISCUSSION

11.1 Key results

This PASS study was conducted by means of a cross-sectional survey of a sample of HCP respondents and patient respondents in Denmark, France, Germany, Greece, Norway, Sweden, and the UK.

The overall objective of this study was to evaluate the effectiveness of the educational material risk minimization measures being implemented in the EU in HCP respondents who were prescribing and/or administering CZP and in patient respondents who were prescribed CZP.

Two surveys were used for the qualitative collection of data, and these were administered locally:

- Healthcare professional survey – for use with prescribing physicians and HCP respondents who administered CZP
- Patient survey – for use with patient respondents who had received CZP

CZP educational materials receipt, awareness, access, and understanding

- Healthcare professional respondents
 - The majority of HCP respondents in France (73%), Germany (100%), the UK (74%), and Greece (96%) received the CZP Prescriber Guide, though receipt was lower in the Nordics (44%). In each country, the proportion of HCP respondents who received the CZP Prescriber Guide was above or within the EMA usage target of 35% to 60%.
 - Of the HCP respondents who read the CZP Prescriber Guide (89%), a majority understood (97%) the CZP Prescriber guide overall and by country for France (91% and 95%, respectively), Germany (100% each), the UK (84% and 95%, respectively), Greece (96% and 100%, respectively), and the Nordics (84% and 96%, respectively).
 - Overall, the CZP Prescriber Guide was well understood with 164 HCP respondents (97%) understanding all information. The proportions of HCP respondents who

understood all information in the CZP Prescriber Guide were high and similar between countries ($\geq 95\%$ in each country).

- Overall, 113 HCP respondents (67%) indicated they received the Patient Alert Card. In individual countries, the proportions of HCP respondents who indicated they received the Patient Alert Card were higher in Germany (25 HCP respondents [96%]) and Greece (34 HCP respondents [85%]) compared with France (18 HCP respondents [45%]) and the UK (22 HCP respondents [55%]).
- Overall, the proportion of HCP respondents who read the Patient Alert Card was high (107 HCP respondents [95%]). The majority of HCP respondents thought that the Patient Alert Card was extremely useful (18 HCP respondents [11%]) or very useful (81 HCP respondents [48%]).
- Patient respondents
 - In total, 73% of patient respondents received the Patient Alert Card, including 52% of patient respondents in France, 100% of patient respondents in Germany, 75% of patient respondents in the UK, 88% of patient respondents in Greece, and 52% of patient respondents in the Nordics, which was above the EMA usage target of 35% to 50% in each country.
 - Overall, the proportion of patient respondents who read the Patient Alert Card was high (91%) and ranged from 100% in the UK and the Nordics to 88% in Germany, which was above the EMA target of 35% to 50%. The proportion of patient respondents who indicated they understood all the information displayed in the Patient Alert Card for CZP was high (61 patient respondents [97%]), and ranged from 2 patient respondents (100%) in the Nordics to 14 patient respondents (93%) in Germany.

Knowledge related to important CZP safety information

- Healthcare professional respondents
 - In general, the majority of HCP respondents were able to correctly identify which risks were and were not associated with CZP. The most common correctly identified risk that was associated with CZP was serious bacterial infection (149 HCP respondents [88%]).
 - Overall, the proportions of HCP respondents who correctly answered questions regarding the use of CZP with ‘True’ was high and ranged from 162 HCP respondents (96%) to 144 HCP respondents (85%). The proportions of HCP respondents who correctly answered questions regarding the use of CZP as ‘False’ ranged from 121 HCP respondents (72%) to 56 HCP respondents (33%).
- Patient respondents
 - The majority of patient respondents were able to correctly respond to each statement about CZP (range: 61 patient respondents [97%] to 41 patient respondents [65%]). The most common correctly identified statement was ‘You have to contact your doctor in case of persistent fever or infection’ (response of ‘True’) (61 patient respondents [97%]).

11.2 Limitations

There were small numbers of patient respondents in some countries (ie, the UK and the Nordics) and inter-country variability was observed in patient respondent responses.

12 OTHER INFORMATION

Not applicable.

13 CONCLUSIONS

The results of this PASS showed that the majority of HCP respondents and patient respondents read and understood the information that provided guidance on the safety profile and safe use of CZP. Furthermore, the percentage of respondents was within the target values agreed with EMA. The majority of HCP respondents and patient respondents also found these materials useful or helpful in understanding the safety profile of CZP.

14 REFERENCES

Not applicable.

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