Protocol Registration Form

Identification

Unique Study ID:	1199-0375
Brief Title:	A study based on medical records that looks at the characteristics of idiopathic pulmonary fibrosis patients grouped by the type of medication they are taking NOTE: Brief Title should have no more than 120 characters
Acronym:	
Official Title:	Characteristics of IPF patients initiating nintedanib, pirfenidone or no antifibrotic treatment in the US

Secondary Ids

Secondary Id	Id Type	Id Domain

Status

Record Verification Date:	Verification Date is entered/updated on the Create Submission screen.
Overall Recruitment Status:	Completed
Study Start Date:	2018-12-19 Actual
Primary Completion Date:	2019-05-14 Actual
Study Completion Date:	2019-05-14 Actual

Sponsor

Responsible Party:	Sponsor
Sponsor:	Boehringer Ingelheim
Collaborators:	

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
U.S. FDA IND/IDE Study:	
Human Subjects Protection Review:	Approved
Board Number:	January 30, 2019
Board Name:	New England Independent Review Board (NEIRB)
Board Affiliation:	Western Institutional Review Board (WIRB)
Board Contact:	617-243-3924 197 First Avenue, Suite 250, Needham MA 02494
Data Monitoring Committee:	No
Is FDA Regulated Intervention:	No

IPD Sharing

Plan to Share IPD:	Yes
Plan Description:	After the study is completed and the primary manuscript is accepted for publishing, researchers can use this following link https:// trials.boehringer-ingelheim.com/trial_results/ clinical_submission_documents.html to request access to the clinical study documents regarding this study, and upon a signed “Document Sharing Agreement”. Also, Researchers can use the following link http://trials.boehringeringelheim. com/ to find information in order to request access to the clinical study data, for this and other listed studies, after the submission of a research proposal and according to the terms outlined in the website. The data shared are the raw clinical study data sets.

Supporting Information:	Study Protocol Statistical Analysis Plan (SAP) Clinical Study Report (CSR)
Time Frame:	After all regulatory activities are completed in the US and EU for the product and indication, and after the primary manuscript has been accepted for publication.
Access Criteria:	For study documents – upon signing of a ‚Document Sharing Agreement'. For study data – 1. after the submission and approval of the research proposal (checks will be performed by both the independent review panel and the sponsor, including checking that the planned analysis does not compete with sponsor's publication plan); 2. and upon signing of a ‚Data Sharing Agreement'.
URL:	https://trials.boehringer-ingelheim.com WARNING: URL does not appear to link to a functioning web page.

Description

Brief Summary:	To understand differences in characteristics of Idiopathic Pulmonary Fibrosis (IPF) patients who are prescribed nintedanib compared to those who are prescribed pirfenidone.
Detailed Description:	NOTE: Detailed Description has not been entered.

Conditions

Conditions or Focus of Study:	Idiopathic Pulmonary Fibrosis
Keywords:	

Design

Study Type:	Observational
Observational Study Model:	Cohort
Time Perspective:	Retrospective
Biospecimen Retention:	None Retained
Biospecimen Description:	
Enrollment:	13264 Actual
Number of Groups/Cohorts:	1

Interventions

Groups

Group/Cohort	Description
Subjects with Idiopathic Pulmonary Fibrosis	NOTE: Group/Cohort Description has not been entered.
NOTE: Group/Cohort Description has not been entered.	

Interventions

Intervention Name*	Type*	Groups/Cohorts	Description *§	Other Names[*]
Nintedanib	Drug	Subjects with Idiopathic Pulmonary Fibrosis	Nintedanib initiators	
NOTE: Intervention Other Names have not been specified				
Pirfenidone	Drug	Subjects with Idiopathic Pulmonary Fibrosis	Pirfenidone initiators	
NOTE: Intervention Other Names have not been specified				
Untreated Cohort	Other	Subjects with Idiopathic Pulmonary Fibrosis	Untreated	

Outcome Measures

Primary Outcome Measures

Outcome Measure	TimeFrame	Description
The absolute standardized differences (ASD) to baseline patient characteristics	up to 12 months	

NOTE: Outcome Measure Description has not been entered.

Secondary Outcome Measures

Outcome Measure	TimeFrame	Description
probability of receiving nintedanib vs. pirfenidone and that of receiving nintedanib or pirfenidone vs. no treatment based on patient characteristic	up to 12 months	
NOTE: Outcome Measure Description has not been entered.		

Other Pre-specified Outcome Measures

Outcome Measure	TimeFrame	Description

Eligibility

Study Population Description:	The study population will consist of the following three mutually exclusive cohorts: 1. Nintedanib initiators, consisting of adult IPF patients who newly initiated nintedanib treatment 2. Pirfenidone initiators, consisting of adult IPF patients who newly initiated pirfenidone treatment 3. Untreated cohort, consisting of adult IPF patients without any prescription for antifibrotic treatment (i.e., no prescription for nintedanib nor pirfenidone)
Sampling Method:	Non-Probability Sample
Sex:	All
Gender Based:	
Age Limits:	Min. Age: 40 Years Max. Age: N/A
Accepts Healthy Volunteers:	No
Eligibility Criteria:	Inclusion Criteria: -With ≥ 1 diagnosis for IPF (the International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] codes 516.3, 516.31, 515, or ICD-10-CM codes J84.112) in the EMR between October 1, 2013 to April 30, 2018 -With ≥ 1 prescription for nintedanib between October 1, 2014 and April 30, 2018 (the selection window) -The date of the first prescription will be defined as the index date -With ≥ 1 record in the EMR database during the 12 months prior to the index date (the pre-index period) -With ≥ 1 diagnosis of IPF during the 12 months prior to the index date -Age ≥ 40 on the index date -IQVIA will explore also requiring ≥ 1 chest CT scan before first IPF diagnosis during the pre-index period Exclusion Criteria: -With ≥ 1 diagnosis of other known causes of interstitial lung disease (ILD) on the date of or after the first IPF diagnosis during the pre-index period -Other known causes of ILD include conditions such as systemic sclerosis, rheumatoid arthritis, systemic lupus erythematosus, dermatomyositis, polymyositis, Sjögren disease, and hypersensitivity pneumonitis (ICD-9-CM codes 135, 237.7, 272.7, 277.3, 277.8, 446.21, 446.4, 495, 500–505, 506.4, 508.1, 508.8, 516.0, 516.1, 516.32 –516.37, 516.2, 516.8, 516.9, 517.0, 517.2, 517.8, 518.3, 555, 710.0, 710.0–710.4, 714.0, 714.81, 720, and 759.5, or ICD-10-CM equivalent codes) -With ≥ 1 prescription for nintedanib prior to the index date -With ≥ 1 prescription for pirfenidone prior to or on the index date

Locations

Contact

Central Contact:	Boehringer Ingelheim 1-800-243-0127 clintriage.rdg@boehringer-ingelheim.com
Central Contact Backup:	

Study Officials/Investigators

First	MI	Last	Degree	Role	Organizational Affiliation
NOTE: Study Official is required by the WHO and ICMJE.					

Locations

ID	Facility	City	State/Province	Postal Code	Country	Recruitment Status	Contact	Contact Backup	Investigator	Send to ClinicalTrials.gov	Allow Import to Overwrite	Submitted
	Plymouth Meeting	Plymouth	Pennsylvania	19462	USA	Active, not recruiting	Chakkarin Burudpakdee 610-244-2025 Chakkarin.Burudpakdee@iqvia.com			✓		

References

Citations

PubMed ID	Results Reference	Citation

Links

URL	Description

Available Study Data/Documents

Document Type	Document Type Other	URL	Identifier	Comments