Disclaimer

The following report(s) provides findings from an FDA-initiated query using Sentinel. While Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Sentinel, and seeking to better understand Sentinel capabilities.

Data obtained through Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from Sentinel in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview for Report: cder_iqp_wp024

Request ID: cder_ipq_wp024

Requester: Center for Drug Evaluation and Research (CDER)

Request Description: This query is part of ongoing active monitoring activities for ibrexafungerp. Ibrexafungerp is an antifungal agent used to treat vulvovaginal candidiasis (VVC) in post-menarchal women and is contraindicated for use in pregnancy due to findings of severe fetal toxicity. This query aims to identify early signaling of ibrexafungerp use in pregnant patients. The FDA's Sentinel Electronic Health Record (EHR) data from TriNetX was used to complete the query.

Data Source: We ran this query on June 23, 2022. This query contains data from 74 health care organizations (HCOs), provided through the TriNetX Live™ platform in their USA Network from June 1, 2020 to May 26, 2022.
TriNetX aggregates EHR systems data from its partner HCOs to create queryable datasets. TriNetX datasets primarily comprise clinical patient data such as demographics, diagnoses, procedures, labs, and medications. For more information on the TriNetX Live™ platform and the TriNetX data visit their website here: https://trinetx.com/

Study Design: A descriptive approach was used to characterize patients with evidence of ibrexafungerp use and a pregnancy test. This was done using the Query Builder module in the TriNetX Live™ platform.

Exposures of Interest: Our exposures of interest for each cohort were as follows:

1) Evidence of any ibrexafungerp
2) Evidence of ibrexafungerp with a pregnancy test in the seven days prior through one day after ibrexafungerp
3) Evidence of ibrexafungerp with a positive pregnancy test in the seven days prior through one day after ibrexafungerp
4) Evidence of ibrexafungerp with a negative pregnancy test in the seven days prior through one day after ibrexafungerp ibrexafungerp
5) Evidence of a positive pregnancy test with ibrexafungerp in the 90 days after the test
6) Evidence of a positive pregnancy test with ibrexafungerp in the 90 days after the test AND no evidence of spontaneous abortion in the 90 days prior to ibrexafungerp

All cohorts were duplicated to restrict age to certain categories (<15, 15-45, and ≥45 years), and race (Asian, Black or African American, Other, Unknown, and White).

We defined exposures using RxNorm medication terms, Logical Observation Identifiers, Names and Codes (LOINC) laboratory codes, and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes. Please see Appendix A for the full list of codes used to define exposures in this request.

We defined inclusions using RxNorm medication terms, Logical Observation Identifiers, Names and Codes (LOINC) laboratory codes, Healthcare Common Procedure Coding System (HCPCS) procedure codes, and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes. We defined exclusions using Logical Observation Identifiers, Names and Codes (LOINC) laboratory codes, Healthcare Common Procedure Coding System (HCPCS) procedure codes, and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes. Please see Appendix B for the full list of codes used to define inclusions and exclusions in this request.

Cohort Eligibility Criteria: Patients of female sex were included in the cohort. For age-restricted cohorts, patients were required to meet the age criteria at the time of their ibrexafungerp use.

Please see Appendices C and D for the specifications of parameters used in this request and a design diagram.

Overview for Report: cder_iqp_wp024

Limitations: Algorithms and mapping of source data to the data model are imperfect and susceptible to misclassification. Additionally, EHR data in the US lacks longitudinality. The information before or after patients' healthcare encounters could be missing, especially if patient care was administered across different HCOs that might not participate in the TriNetX USA network. We are unable to determine if absence of evidence of a condition implies a true absence of a condition or if the condition was not observed in the data.

A subset of HCOs contributing data across the TriNetX Networks date shift between 1 and 365 days in either direction at the level of the patient record. All records for a patient are shifted the same number of days. Data should be interpreted with these limitations in mind, especially when they are relevant to a specific calendar period, like an approval date.

All counts provided through the TriNetX Live™ platform are rounded up to the nearest 10 to protect patient privacy. This rounding affects error, especially as sample sizes decrease. Error due to rounding can range from <0.09% when sample sizes are >10,000 to nearly 20% as sample sizes drop. Thus, all estimates should be interpreted as ranges, and small sample sizes should be interpreted with caution. Additionally, percentages are calculated based on these rounded numerators and denominators. Thus, due to rounding, the sum of each value in a category may not total to 100%.

Notes: We ran this query on June 23, 2022. A re-run of this query for the same query period in the future may not yield the same results owing to the dynamic nature of the TriNetX Live™ network. Please contact the Sentinel Operations Center (info@sentinelsystem.org) for questions and to provide comments/suggestions for future enhancements to this document. For more information on Sentinel's querying in the TriNetX platform, please refer to the Sentinel Website (https://www.sentinelinitiative.org/methods-data-tools/methods/trinetx-rapid-querying).

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Glossary of Terms for Analyses Using TriNetX Live™ Platform*

Characteristic - A medical fact (e.g., diagnosis, procedure, lab result) that occurred on or before the cohort-defining index event.

Explore Cohort - A description module on the TriNetX platform that presents a clinical profile of patients in a given cohort. Patient counts are rounded up to the nearest 10 before percentages are calculated, so the sum each of the values in one category may not total to 100%.

Date Shifting - A data obfuscation technique that some HCOs use to preserve patient privacy. Date shifting entails assigning each patient a random number of days (eg, -365 to +365 days) and consistently adjusting each of their dates by that number of days, thus maintaining temporal relationships between records within a single patient.

Fact - (Medical Fact) A unit of utilization that represents a medical observation on a patient (e.g., diagnosis, procedure, clinical observation).

Filter - A method of limiting terms included in queries to a specific subset of data. Filters include age at time of event, data source (electronic health record or natural language processing); brand name, route, and strength for medication terms; occurrence (first or most recent) for lab terms; and priority for diagnosis and procedure terms.

Group - A series of codes and terms defined with Boolean logic that are used to create a query cohort. For each group, users have the ability to specified time periods of interest, and the number of instances that the group must occur for cohort entry.

> **Subgroup -** Within a group, additional subgroups can be specified to define temporal relationships between the terms in the subgroup (e.g., terms in subgroup B must occur within 5 days after terms in subgroup A). Users can require that these temporal constraints be applied to the 1) first, 2) last, or 3) any instance of each subgroup.

Health Care Organization (HCO) - Organizations that contribute electronic healthcare record data to the TriNetX data networks. HCOs include academic institutions and community health provider systems and a single HCO may contain one or more individual sites or facilities.

Index - The first date when a patient meets all of the cohort-defining criteria. In Analytics modules, the index can be defined as the date when a patient meets all of the cohort criteria, or only one specific group's criteria.

Module - A subsection of the TriNetX platform that performs a distinct functionality. Cohorts are created using the Query Builder module. Descriptive modules include Healthcare Organizations, Explore Cohorts, Rate of Arrival, Summary Statistics, and Analyze Criteria. Advanced analytic modules include Analyze Outcomes, Compare Outcomes, Compare Cohorts, Treatment Pathways, and Incidence and Prevalence.

Network - An aggregation of HCOs contributing data to the platform. Multiple networks are available for querying on the platform; the different networks represent subsets of HCOs organized by date-shifting practices or availability of downloadable datasets.

Outcome - A medical fact (e.g., diagnosis, procedure, lab result) that occurred on or after the cohort-defining index event.

Query - In the TriNetX platform, a query is a distinct cohort with a unique set of terms and logic. Query cohorts are created using the Query Builder platform module.

Risk - In Advanced Analytics modules, risk refers to the percentage of patients in each cohort with the specified outcome of interest.

Priority - An indication whether the code was the condition that the provider spent the most time evaluating or treating during a visit. Possible values include primary, secondary, or unknown.

Term - The codes used to specify patient cohort criteria in a query. Code options include diagnoses, procedures, medications, labs, demographics, genomics, and visits. Terms can be linked together using and/or Boolean logic. TriNetX also creates terms that group together multiple medical codes into single clinical concepts.

Cannot Have Term - A category of terms within a query group that patients must not have evidence of to be included in the cohort.

Must Have Term - A category of terms within a query group that patients must have evidence of to be included in the cohort.

Time Constraint - used to define time periods of interest for each group within a query. Time constraints can be defined relative to the date the query was run (e.g., any time before today), or defined based on specific dates (e.g., January 1, 2015 to September 30, 2020).

Treatment Pathway - In Advanced Analytics modules, the Treatment Pathways module returns the order in which patients received treatment and the prevalence of treatments, including combination of medications, following an index event.

TriNetX Codes - For commonly used laboratory terms, TriNetX aggregates Logical Observation Identifiers Names and Codes (LOINC) laboratory codes at a clinically significant level to new queryable TNX:LAB terms.

Visit - A type of term used to specify the type of medical encounter or facility where the encounter was recorded. Visit terms are derived by TriNetX from the source data. Visits are recorded separately from the codes or labs that occurred during the encounter; care settings are not attached to individual codes. Values for visit terms include: ambulatory, emergency, field, home health, inpatient encounter, inpatient acute, inpatient non-acute, laboratory, observation, pharmacy, pre-admission, short stay, virtual, and unknown.

*all terms may not be used in this report

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Table 1. Demographics Among Female Patients with Various Definitions of "ibrexafungerp Exposure" from June 1, 2020 - May 26, 2022

	Evidence of any ibrexafungerp		Evidence of ibrexafungerp with a pregnancy test in the 7 days prior through 1 day after ibrexafungerp		Evidence of ibrexafungerp with a positive pregnancy test in the 7 days prior through 1 day after ibrexafungerp		Evidence of ibrexafungerp with a negative pregnancy test in the 7 days prior through 1 day after ibrexafungerp		Evidence of a positive pregnancy test with ibrexafungerp in the 90 days after the test		Evidence of a positive pregnancy test with ibrexafungerp in the 90 days after the test AND no evidence of spontaneous abortion in the 90 days prior to ibrexafungerp	
Characteristics	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**	**Number**	**Percent**
Total Patients	300	100.0%	20	100.0%	10	100.0%	10	100.0%	10	100.0%	10	100.0%
Demographics												
Age (mean ± SD)												
<15 years	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
15-45 years	210	70.0%	20	100.0%	10	100.0%	10	100.0%	10	100.0%	10	100.0%
>45 years	100	33.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Race												
Asian	10	3.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Black or African American	80	26.7%	10	50.0%	0	0.0%	10	100.0%	10	100.0%	0	0.0%
Other[1]	10	3.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Unknown	30	10.0%	10	50.0%	0	0.0%	10	100.0%	0	0.0%	0	0.0%
White	190	63.3%	10	50.0%	10	100.0%	10	100.0%	10	100.0%	10	100.0%

NOTE: TriNetX obfuscates patient counts to safeguard protected health information (PHI), and percentages are calculated based on numerators and denominators rounded up to the nearest 10. Thus, all values in this table are actually ranges (i.e. 10 represents values from 1-10, 20 represents values 11-20, etc.), and the sum of each value in a category may not total to 100%.

[1]Other" race includes American Indian, Alaska Native, Native Hawaiian, or Other Pacific Islander.

Appendix A. List of RxNorm Medication Terms, Logical Observation Identifiers, Names and Codes (LOINC) Laboratory Codes, and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes Used to Define Exposures in this Request

Code	Description	Code Category	Code Type
	Ibrexafungerp		
2560213	Ibrexafungerp	Medication	RxNorm
	Pregnancy Test - Positive		
80385-8	Choriogonadotropin (pregnancy test) [Presence] in Serum by Rapid immunoassay	Laboratory Test	LOINC
2118-8	Choriogonadotropin (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2106-3	Choriogonadotropin (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
80384-1	Choriogonadotropin (pregnancy test) [Presence] in Urine by Rapid immunoassay	Laboratory Test	LOINC
2110-5	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2112-1	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
Z32.01	Encounter for pregnancy test, result, positive	Diagnosis	ICD-10-CM

Appendix B. List of Logical Observation Identifiers, Names and Codes (LOINC) Laboratory Codes, Healthcare Common Procedure Coding System (HCPCS), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes, and RxNorm Medication Terms Used to Define Inclusions and Exclusions in this Request

Code	Description	Code Category	Code Type
	INCLUSIONS		
	Pregnancy Test		
80385-8	Choriogonadotropin (pregnancy test) [Presence] in Serum by Rapid immunoassay	Laboratory Test	LOINC
2118-8	Choriogonadotropin (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2106-3	Choriogonadotropin (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
80384-1	Choriogonadotropin (pregnancy test) [Presence] in Urine by Rapid immunoassay	Laboratory Test	LOINC
2110-5	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2112-1	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
66562-0	Pregnancy test required [PhenX]	Laboratory Test	LOINC
66563-8	Pregnancy test result [PhenX]	Laboratory	LOINC
81025	Urine pregnancy test, by visual color comparison methods	Procedure	HCPCS
Z32.0	Encounter for pregnancy test, result	Diagnosis	ICD-10-CM
Z32.00	Encounter for pregnancy test, result, unknown	Diagnosis	ICD-10-CM
	Pregnancy Test - Positive		
80385-8	Choriogonadotropin (pregnancy test) [Presence] in Serum by Rapid immunoassay	Laboratory Test	LOINC
2118-8	Choriogonadotropin (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2106-3	Choriogonadotropin (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
80384-1	Choriogonadotropin (pregnancy test) [Presence] in Urine by Rapid immunoassay	Laboratory Test	LOINC
2110-5	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2112-1	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
Z32.01	Encounter for pregnancy test, result, positive	Diagnosis	ICD-10-CM
	Pregnancy Test - Negative		
80385-8	Choriogonadotropin (pregnancy test) [Presence] in Serum by Rapid immunoassay	Laboratory Test	LOINC
2118-8	Choriogonadotropin (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2106-3	Choriogonadotropin (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC

Appendix B. List of Logical Observation Identifiers, Names and Codes (LOINC) Laboratory Codes, Healthcare Common Procedure Coding System (HCPCS), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes, and RxNorm Medication Terms Used to Define Inclusions and Exclusions in this Request

Code	Description	Code Category	Code Type
80384-1	Choriogonadotropin (pregnancy test) [Presence] in Urine by Rapid immunoassay	Laboratory Test	LOINC
2110-5	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2112-1	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
Z32.02	Encounter for pregnancy test, result, negative	Diagnosis	ICD-10-CM
	Ibrexafungerp		
2560213	Ibrexafungerp	Medication	RxNorm
	EXCLUSIONS		
	Pregnancy Test - Positive		
80385-8	Choriogonadotropin (pregnancy test) [Presence] in Serum by Rapid immunoassay	Laboratory Test	LOINC
2118-8	Choriogonadotropin (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2106-3	Choriogonadotropin (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
80384-1	Choriogonadotropin (pregnancy test) [Presence] in Urine by Rapid immunoassay	Laboratory Test	LOINC
2110-5	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Serum or Plasma	Laboratory Test	LOINC
2112-1	Choriogonadotropin.beta subunit (pregnancy test) [Presence] in Urine	Laboratory Test	LOINC
Z32.01	Encounter for pregnancy test, result, positive	Diagnosis	ICD-10-CM
	Spontaneous Abortion		
59821	Treatment of missed abortion, completed surgically; second trimester	Procedure	HCPCS
59820	Treatment of missed abortion, completed surgically; first trimester	Procedure	HCPCS
59812	Treatment of incomplete abortion, any trimester, completed surgically	Procedure	HCPCS
01965	Anesthesia for incomplete or missed abortion procedures	Procedure	HCPCS
O02.1	Missed abortion	Diagnosis	ICD-10-CM
O03	Spontaneous abortion	Diagnosis	ICD-10-CM
O03.0	Genital tract and pelvic infection following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.1	Delayed or excessive hemorrhage following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.2	Embolism following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.3	Other and unspecified complications following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.30	Unspecified complication following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.31	Shock following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.32	Renal failure following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.33	Metabolic disorder following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.34	Damage to pelvic organs following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.35	Other venous complications following incomplete spontaneous abortion	Diagnosis	ICD-10-CM

Appendix B. List of Logical Observation Identifiers, Names and Codes (LOINC) Laboratory Codes, Healthcare Common Procedure Coding System (HCPCS), International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes, and RxNorm Medication Terms Used to Define Inclusions and Exclusions in this Request

Code	Description	Code Category	Code Type
O03.36	Cardiac arrest following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.37	Sepsis following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.38	Urinary tract infection following incomplete spontaneous abortion	Diagnosis	ICD-10-CM
O03.39	Incomplete spontaneous abortion with other complications	Diagnosis	ICD-10-CM
O03.4	Incomplete spontaneous abortion without complication	Diagnosis	ICD-10-CM
O03.5	Genital tract and pelvic infection following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.6	Delayed or excessive hemorrhage following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.7	Embolism following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.8	Other and unspecified complications following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.80	Unspecified complication following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.81	Shock following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.82	Renal failure following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.83	Metabolic disorder following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.84	Damage to pelvic organs following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.85	Other venous complications following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.86	Cardiac arrest following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.87	Sepsis following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.88	Urinary tract infection following complete or unspecified spontaneous abortion	Diagnosis	ICD-10-CM
O03.89	Complete or unspecified spontaneous abortion with other complications	Diagnosis	ICD-10-CM
O03.9	Complete or unspecified spontaneous abortion without complication	Diagnosis	ICD-10-CM

Appendix C. Specifications Defining Parameters for this Request

GROUPS 1a-1i: IBREXAFUNGERP USERS	
Cohort 1a: ibrexafungerp user	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
FILTERED BY AGE GROUP (<15, 15-45, >45 YEARS)	
Cohort 1b: ibrexafungerp user + <15	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: <15 years	6/1/2020 - Most recent data available
Cohort 1c: ibrexafungerp user + 15-45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: 15-45 years	6/1/2020 - Most recent data available
Cohort 1d: ibrexafungerp user + >45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: >45 years	6/1/2020 - Most recent data available
FILTERED BY RACE: OTHER, ASIAN, BLACK, WHITE, UNKNOWN	
Cohort 1e: ibrexafungerp user + Other	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
American Indian or Alaska Native OR	
Native Hawaiian or Other Pacific Islander	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available

Appendix C. Specifications Defining Parameters for this Request

GROUPS 1a-1i: IBREXAFUNGERP USERS	
Cohort 1f: ibrexafungerp user + Asian	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Asian	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
Cohort 1g: ibrexafungerp user + Black	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Black	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
Cohort 1h: ibrexafungerp user + White	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
White	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
Cohort 1i: ibrexafungerp user + Unknown	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Cannot Have:	
American Indian or Alaska Native OR Native Hawaiian OR Pacific Islander OR Asian OR Black OR White	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available

Appendix C. Specifications Defining Parameters for this Request

GROUPS 2a-2i: IBREXAFUNGERP USER + PREGNANCY TEST	
Cohort 2a: ibrexafungerp user	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp
FILTERED BY AGE GROUP (<15, 15-45, >45 YEARS)	
Cohort 2b: ibrexafungerp user + <15	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: <15 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp
Cohort 2c: ibrexafungerp user + 15-45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: 15-45 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp
Cohort 2d: ibrexafungerp user + >45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: >45 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 2a-2i: IBREXAFUNGERP USER + PREGNANCY TEST	
FILTERED BY RACE: OTHER, ASIAN, BLACK, WHITE, UNKNOWN	
Cohort 2e: ibrexafungerp user + Other	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
American Indian or Alaska Native OR	
Native Hawaiian or Other Pacific Islander	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp
Cohort 2f: ibrexafungerp user + Asian	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Asian	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp
Cohort 2g: ibrexafungerp user + Black	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Black	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 2a-2i: IBREXAFUNGERP USER + PREGNANCY TEST	
Cohort 2h: ibrexafungerp user + White	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
White	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp
Cohort 2i: ibrexafungerp user + Unknown	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Cannot Have:	
American Indian or Alaska Native OR Native Hawaiian OR Pacific Islander OR Asian OR Black OR White	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 3a-3i: IBREXAFUNGERP USER + POSITIVE PREGNANCY TEST	
Cohort 3a: ibrexafungerp user + POS test	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
FILTERED BY AGE GROUP (<15, 15-45, >45 YEARS)	
Cohort 3b: ibrexafungerp user + POS test + <15	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: <15 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 3c: ibrexafungerp user + POS test + 15-45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: 15-45 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 3d: ibrexafungerp user + POS test + >45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: >45 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 3a-3i: IBREXAFUNGERP USER + POSITIVE PREGNANCY TEST	
FILTERED BY RACE: OTHER, ASIAN, BLACK, WHITE, UNKNOWN	
Cohort 3e: ibrexafungerp user + POS test + Other	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
American Indian or Alaska Native OR	
Native Hawaiian or Other Pacific Islander	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 3f: ibrexafungerp user + POS test + Asian	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Asian	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 3g: ibrexafungerp user + POS test + Black	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Black	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 3a-3i: IBREXAFUNGERP USER + POSITIVE PREGNANCY TEST	
Cohort 3h: ibrexafungerp user + POS test + White	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
White	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 3i: ibrexafungerp user + POS test + Unknown	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Cannot Have:	
American Indian or Alaska Native OR Native Hawaiian OR Pacific Islander OR Asian OR Black OR White	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 4a-4i: IBREXAFUNGERP USER + NEGATIVE PREGNANCY TEST	
Cohort 4a: ibrexafungerp user + NEG test	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
FILTERED BY AGE GROUP (<15, 15-45, >45 YEARS)	
Cohort 4b: ibrexafungerp user + NEG test + <15	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: <15 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 4c: ibrexafungerp user + NEG test+ 15-45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: 15-45 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 4a-4i: IBREXAFUNGERP USER + NEGATIVE PREGNANCY TEST	
Cohort 4d: ibrexafungerp user + NEG test + >45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
ibrexafungerp	
Filter: Age at event: >45 years	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
FILTERED BY RACE: OTHER, ASIAN, BLACK, WHITE, UNKNOWN	
Cohort 4e: ibrexafungerp user + NEG test + Other	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
American Indian or Alaska Native OR	
Native Hawaiian or Other Pacific Islander	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 4f: ibrexafungerp user + NEG test + Asian	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Asian	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 4a-4i: IBREXAFUNGERP USER + NEGATIVE PREGNANCY TEST	
Cohort 4g: ibrexafungerp user + NEG test + Black	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Black	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 4h: ibrexafungerp user NEG test + White	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
White	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp
Cohort 4i: ibrexafungerp user + NEG test + Unknown	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Cannot Have:	
American Indian or Alaska Native OR Native Hawaiian OR Pacific Islander OR Asian OR Black OR White	
Subgroup 1A:	
Must Have:	
ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Pregnancy Test - result filter: Negative	[-7,1] Any instance of ibrexafungerp
Cannot Have:	
Pregnancy Test - result filter: Positive	[-7,1] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 5a-5i: POSITIVE PREGNANCY TEST + IBREXAFUNGERP	
Cohort 5a: POS test + ibrexafungerp	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
FILTERED BY AGE GROUP (<15, 15-45, >45 YEARS)	
Cohort 5b: POS test + ibrexafungerp + <15	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	*6/1/2020 - Most recent data available*
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	*[0,90] Any instance of ibrexafungerp*
Filter: Age at event: <15 years	
Cohort 5c: POS test + ibrexafungerp + 15-45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	*6/1/2020 - Most recent data available*
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	*[0,90] Any instance of ibrexafungerp*
Filter: Age at event: 15-45 years	
Cohort 5d: POS test + ibrexafungerp + >45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	*6/1/2020 - Most recent data available*
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	*[0,90] Any instance of ibrexafungerp*
Filter: Age at event: >45 years	

Appendix C. Specifications Defining Parameters for this Request

GROUPS 5a-5i: POSITIVE PREGNANCY TEST + IBREXAFUNGERP	
FILTERED BY RACE: OTHER, ASIAN, BLACK, WHITE, UNKNOWN	
Cohort 5e: POS test + ibrexafungerp + Other	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
American Indian or Alaska Native OR	
Native Hawaiian or Other Pacific Islander	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Cohort 5f: POS test + ibrexafungerp + Asian	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Asian	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Cohort 5g: POS test + ibrexafungerp + Black	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Black	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 5a-5i: POSITIVE PREGNANCY TEST + IBREXAFUNGERP	
Cohort 5h: POS test + ibrexafungerp + White	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
White	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Cohort 5i: POS test + ibrexafungerp + Unknown	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Cannot Have:	
American Indian or Alaska Native OR Native Hawaiian OR Pacific Islander OR Asian OR Black OR White	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 6a-6i: POSITIVE PREGNANCY TEST + IBREXAFUNGERP + NO SPA	
Cohort 6a: POS test + ibrexafungerp + No SPA	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp
FILTERED BY AGE GROUP (<15, 15-45, >45 YEARS)	
Cohort 6b: POS test + ibrexafungerp + No SPA + <15	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Filter: Age at event: <15 years	
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 6a-6i: POSITIVE PREGNANCY TEST + IBREXAFUNGERP + NO SPA	
Cohort 6c: POS test + ibrexafungerp + No SPA + 15-45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Filter: Age at event: 15-45 years	
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp
Cohort 6d: POS test + ibrexafungerp + No SPA + >45	
Group 1:	**Time Restrictions**
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Filter: Age at event: >45 years	
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 6a-6i: POSITIVE PREGNANCY TEST + IBREXAFUNGERP + NO SPA	
FILTERED BY RACE: OTHER, ASIAN, BLACK, WHITE, UNKNOWN	
Cohort 6e: POS test + ibrexafungerp + No SPA + Other	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
American Indian or Alaska Native OR	
Native Hawaiian or Other Pacific Islander	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp
Cohort 6f: POS test + ibrexafungerp + No SPA + Asian	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Asian	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 6a-6i: POSITIVE PREGNANCY TEST + IBREXAFUNGERP + NO SPA	
Cohort 6g: POS test + ibrexafungerp + No SPA + Black	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
Black	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp
Cohort 6h: POS test + ibrexafungerp + No SPA + White	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Must Have:	
White	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp

Appendix C. Specifications Defining Parameters for this Request

GROUPS 6a-6i: POSITIVE PREGNANCY TEST + IBREXAFUNGERP + NO SPA	
Cohort 6i: POS test + ibrexafungerp + No SPA + Unknown	
Group 1:	**Time Restrictions**
Ungrouped Terms:	
Cannot Have:	
American Indian or Alaska Native OR Native Hawaiian OR Pacific Islander OR Asian OR Black OR White	
Subgroup 1A:	
Must Have:	
Pregnancy test POSITIVE result	6/1/2020 - Most recent data available
And Subgroup 1B:	
Must Have:	
Ibrexafungerp	[0,90] Any instance of ibrexafungerp
Group 2:	**Time Restrictions**
Subgroup 2A:	
Must Have:	
Ibrexafungerp	6/1/2020 - Most recent data available
And Subgroup 2B:	
Cannot Have:	
Spontaneous abortion	[-90,0] Any instance of ibrexafungerp

Appendix D. Design Diagrams of Cohort Entry Requirements

Cohorts 1a-1i

Cohorts 2a-4i*

*Cohorts 2a-2i will look for presence of a pregnancy test only.
*Cohorts 3a-3i will look for a pregnancy test with a positive result only.
*Cohorts 4a-4i will look for a pregnancy test with a negative result only.

Cohorts 5a-6i