CorEvitas Internal Report: Preliminary Counts: [Title]

Prepared for: [Contacts]

Prepared by: [Name and Degree]

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Background

Welcome to the TidyCoRe prelminary count template. This rmarkdown template is designed to help facilitate the reporting of preliminary counts to our subscribers here at CorEvitas.

Database: {PsO, RA, IBD, etc.} registry

Aims

Please create a table that lists all the aims with their appropriate inclusions and exclusions. An example table (from NPF515) has been provided below.

Aim	Inclusion Criteria	Exclusion Criteria
1. To describe biologic initiators by race and treatment group	Initiators/incident users of TNF-inhibitors, IL-17 inhibitors, IL-23 and IL12/23i inhibitors	Missing race
2. To compare the effectiveness of different biologic treatments by race	Initiators/incident users of TNF-inhibitors, IL-17 inhibitors, IL-23 and IL12/23i inhibitors	Missing race
	Baseline and 6-month follow-up	Not persistent at 6 months
		Missing baseline or 6-month effective measures
3. To compare the occurrence of biologic discontinuation at 6 months by race	Initiators/incident users of TNF-inhibitors, IL-17 inhibitors, IL-23 and IL12/23i inhibitors	Missing race
	Baseline and 6-month follow-up/discontinuation	

Cohorts

Separate summaries will be included for each of the characteristics listed below.

Examples include:

- Race
- Ethnicity
- Etc.

Definitions

Please define the terms that would be important for all parties involved to understand.

Examples include:

- *Biologic*: Any therapy that is considered a TNFi, IL-17i, IL-23i, or IL-12/23i class of drugs
  - **Abbvie**: TNFi, IL-17i, IL-23i, IL-12/23i, or aprelimast class of drugs
- *Previous biologic use*:
  - **Bionaïve**: No prior experience with a biologic therapy.
  - **Bioexperienced**: Prior experience with a biologic therapy.
- *Psoriatic Arthritis (PSA)*: Self-diagnosed, Rheumatologist confirmed, or both
- *Moderate/Severe Psoriasis*:
  - **Abbvie**: Any patient with PASI ≥ 12, BSA ≥ 10%, or IGA ≥ 3. Patients with 1 or 2 of these measures missing must meet the moderate/severe definition of at least one of the remaining measures. Patients with all 3 severity measures missing were excluded.
  - **Janssen**: Any patient with BSA ≥ 3% and IGA ≥ 2. Patients with one of these measures missing must meet the moderate/severe definition of the other measure. Patients with both BSA and IGA missing were excluded.
- *Mild Psoriasis*:
  - **Abbvie**: Any patient with PASI < 12, BSA < 10%, and IGA < 3. Patients with 1 or 2 of these measures missing must meet the mild definition of the non-missing measures. Patients with all 3 severity measures missing were excluded.
  - **Janssen**: Any patient with BSA < 3% or IGA < 2. Patients with one of these measures missing must meet the mild definition of the non-missing measure. Patients with both BSA and IGA missing were excluded.

Baseline

Possible definitions:

- **CorEvitas definition of baseline**: Biologic initiation that occurs on that same date as a CorEvitas visit. If the drug started between two CorEvitas visits, a CorEvitas visit within a 42 day window (± 6-weeks) of the drug initiation date was used.
- **CorEvitas definition of baseline (preceding only)**: Biologic initiation that occurs on that same date as a CorEvitas visit. If the drug starts between two visits, the visit prior to initiation is used if the visit occurred within 42 days (6-weeks) of the drug initiation date.
- **Abbvie definition of baseline**: Patients that initiated risakizumab, have a documented start date (e.g. unique confirmed start), and have no documentation errors associated with the start date. Furthermore, the initiation date must be on the date of a CorEvitas visit.

- **Janssen defintion of baseline**: TBD
- **UCB defintion of baseline**: TBD

Outcome windows

Please define the outcome follow-up time points (if applicable, otherwise delete this section) and how they are to be defined and pulled.

- **CorEvitas definition of follow-up time points**: Effectiveness at 6-months following initiation will be ascertained using windows of -1/+3 months. For every 6-month time point following (e.g. 12-, 18-, 24-months), a window of ±3 months will be used. Exact definitions are described below:
  - *6-month follow-up*: 5-9 months from date (stdate or visitdate0)
  - *12-month follow-up*: 9-15 months from date (stdate or visitdate0)
  - The earliest CorEvitas visit in the window will be used in the event that multiple visits occur in the window.

Discontinuation/Persistence (if applicable, otherwise delete this section)

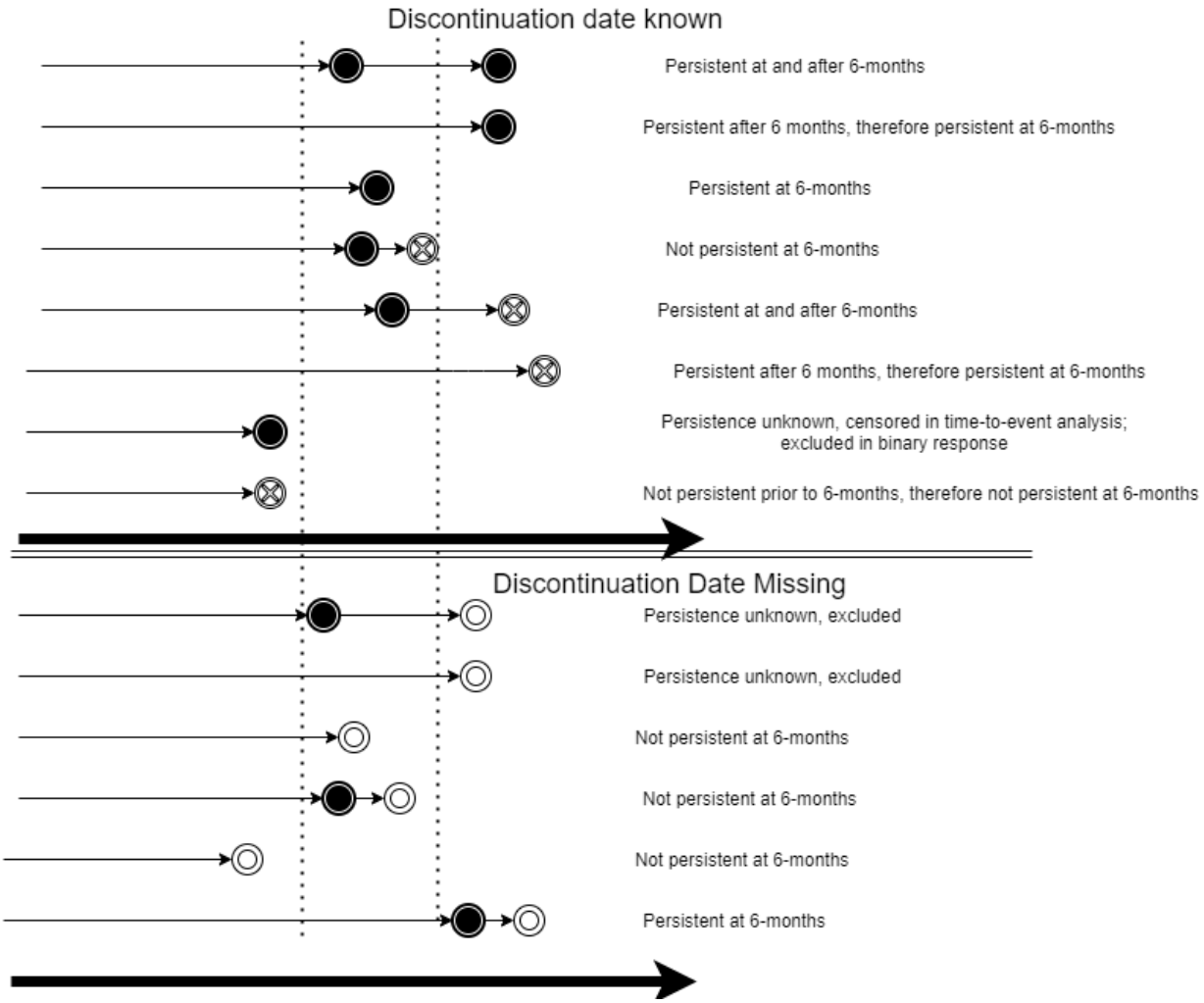
Possible definitions:

- Excluding patients who discontinue therapy prior to their XX follow-up.

Additional notes:

- Pay attention to possible missing discontinuation dates for those who discontinue

Please refer to the chart below to decide which definition/instance of discontinuation is applicable:



Therapy switch (if applicable, otherwise delete this section)

Possible definitions:

- Patients that start a new biologic during the query follow-up period.

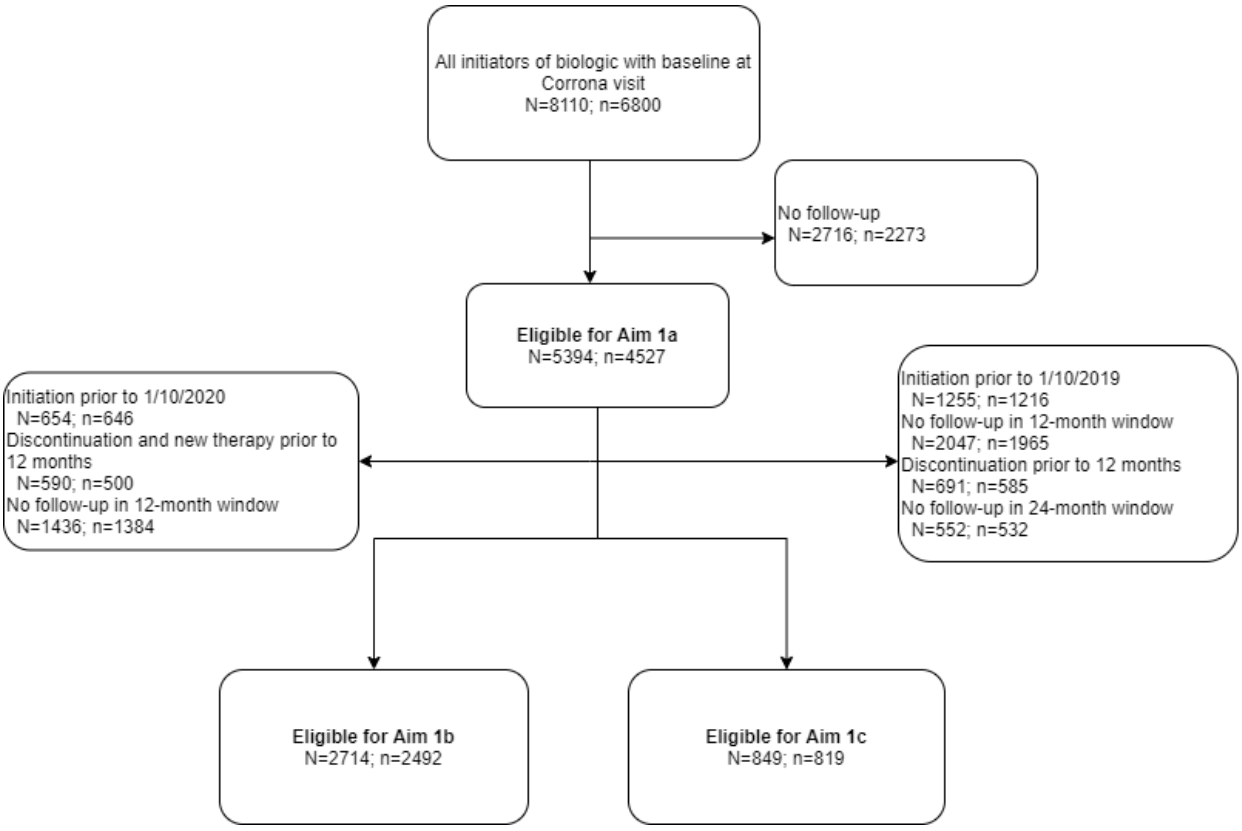
Possible definitions:

- Excluding patients who discontinue therapy and start a new therapy prior to the follow-up period.

Patient Flow Diagram

Data downloaded on {data download date}.

We have included an example as a placeholder. Please replace your organization chart of counts and exclusions/inclusion below:



Tables

The following sections will be tables of counts (incidences or patients) by the study cohorts of interest. This will vary depending on study lead.

Section for Biostatistics use only

The following section is to be used for the biostatistics team and should be **deleted** prior to sharing this document with the subscriber.