Representation of investigational drugs in the OMOP CDM

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INTRO:
- To date, investigational drugs or treatments have to be created as local concepts **making network studies virtually impossible**. Also, the effort for identifying these drugs in the ETL process can be substantial. We therefore propose the creation of an OMOP standardized vocabulary for investigational drugs.

METHODS
1. Requirements were collected and it was ascertained that
   a) A general need for availability of investigational drugs on ingredient level exists
   b) In source data these drugs are often represented with their research code designations
   c) An integration with the regular RxNorm model is warranted, including building relationships to other vocabularies such as HemOnc
2. Several potential sources for identifying investigational drugs together with their various designations or synonyms were investigated and an approach defined.

RESULTS
A combination of potential source vocabularies are targeted to build a comprehensive vocabulary representing investigational drugs including their research designation as synonyms. This will support the ETL process and enable researchers to execute network studies based on unique OMOP concept IDs. We see a particular potential in the oncology area and for the reuse of previously collected clinical trial data.

Reduce effort in ETL and enable network studies by introducing a standardized vocabulary **for investigational drugs.**

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Findings
- A representation of the exposure to investigational drugs in the OMOP CDM can become much easier by making use of a standardized vocabulary providing those, including their pre-market names

- The approach to build a dedicated vocabulary is as follows
  - Identify items on ingredient level as investigational with a certain cut off date (e.g. 10 years back)
  - Introduce alternative designations as synonyms
  - Test for existence of these ingredients in the RxNorm vocabulary and create respective relationships or new ingredients in the RxNorm Extension
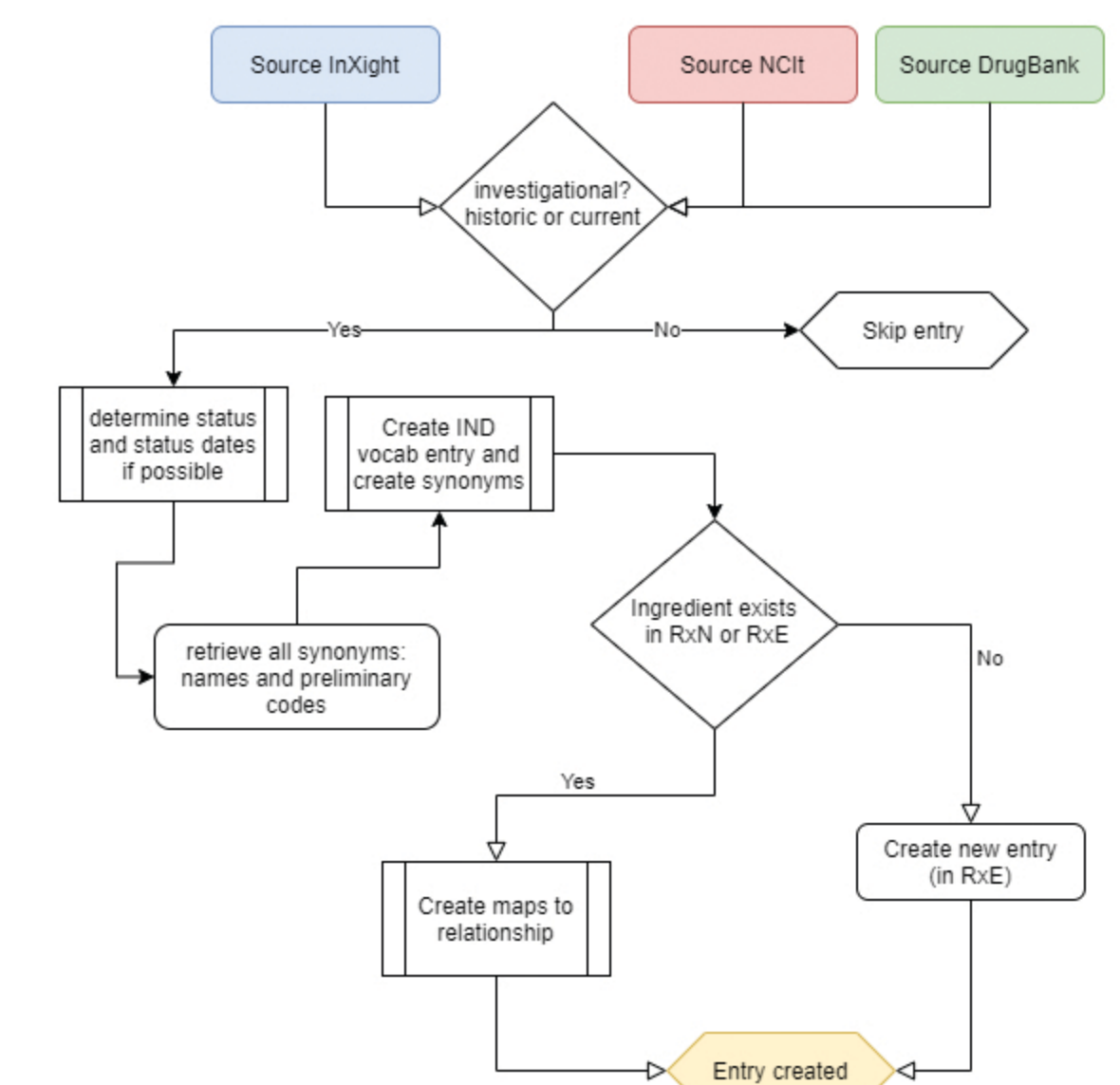
- Most interesting source vocabularies:
  - InXight
  - NCIt drugs
  - DrugBank

- Representation of status and transition between statuses (e.g. investigational > approved) will be subject of more analysis and design

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