

# Submission of Pharmacokinetic Results to ClinicalTrials.gov

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Meeting

June 19, 2018

# Key Changes to ClinicalTrials.gov as of 1/18/2017

- NIH requires results submission for all clinical trials fully/partially funded by NIH, including Phase I and PK
- Summary results required for all primary and secondary outcome measures listed in Protocol Section 9 (statistical) and Section 10 (PK)
- Results due one year after:
  - Primary Completion Date (PCD) or
  - Follow-up complete for secondary outcome measure (if after PCD)
- Statistical Analysis Plan (SAP) for all primary and secondary outcome measures must be submitted

**Non-compliance: Significant fines and grant funds held**

# For Protocols in Development

When objectives/outcome measures being defined:

- Team must ensure primary and secondary outcome measures are clearly defined, including time points
  - Outcome measures to be analyzed by SDAC are in Section 9
  - PK outcome measures are in Section 10
- SDMC and pharmacologists complete 'Plan for ClinicalTrials.gov Results Entry'. Defines:
  - Which PK outcome measures will require results entry
  - Timeline (including sample shipping and running assays)
  - Who is responsible for summarizing results
    - Statistician (from data housed at DMC); or
    - Pharmacologist
  - Who is responsible for results entry into ClinicalTrials.gov

## For Ongoing and Closed Protocols

SDAC and pharmacologists complete 'Plan for ClinicalTrials.gov Results Entry'

But:

- Outcome measures may be less well-defined
- Some secondary outcome measures may actually be more exploratory
- Pharmacologists may need to more clearly define outcome measures and what should be summarized in ClinicalTrials.gov

# When Preparing Results for ClinicalTrials.gov

Pharmacologists/pharmacometricians:

- Prepare SAP for PK outcome measures:
  - Work with statistician to include in SDAC SAP, or
  - Submit separate document for ClinicalTrials.gov
- Use one of two methods for results entry. Either:
  - Send results to statistician using suggested templates (next slide) for statisticians to enter results (preferred), or
  - Work with FHI/SDAC to enter results into ClinicalTrials.gov

# SDAC has Created Templates for Results Entry

Examples for:

1. PK parameter summary statistics (e.g. AUC,  $C_{\min}$  etc.)
2. Numbers of participants achieving a defined PK target

Each template includes :

- Outcome Measure title
- Description
- Time frame
- Analysis population
- Reporting groups
- Simple data summaries
- Statistical analysis

# Summary

For studies with important PK objectives:

- Pharmacologists/pharmacometricians have primary responsibility for defining outcome measures, generating PK parameters, providing SAP, and either:
  - Providing required summaries and/or
  - Ensuring PK data is in DMC database so statistician can generate summaries
- Hard deadlines must be met
- Required information must be prepared leaving sufficient time for sample shipping, assays, generation of summaries, results entry and review
- Up front discussion and agreement on responsibility and timelines will help ensure a smooth transition to the new requirements

# IMPAACT Studies with Primary or Secondary PK Objectives and Results to be Submitted

- Closed or ongoing: 19 studies
- In development: 2 studies
- Study statisticians will work with the study pharmacologists to prepare the 'Plan for ClinicalTrials.gov Results Entry'
- First two studies with PK results submission: P1078 and P1092 (both due by September 2018)