Standard Operating Procedure

Entry of Results into ClinicalTrials.gov Protocol Registration System

Biostatistics and Data Management Core
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The following steps are to be completed by whoever is identified as the lead statistician on a protocol. This may be a fellow if they are responsible the analyses and no statistician has led the analysis. This person will be responsible for authoring all the results.

This process typically starts after a study ends.

Step 1: Review the protocol to understand the primary and secondary objectives. Go to ClinicalTrials.gov to confirm what had been entered.
Note: For older protocols where correlative or other exploratory type objectives are included in the secondary objectives, a discussion will need to take place with the PI on how to handle those results and whether they will be posted. For future studies, any exploratory or tertiary objectives should be labeled as such within the protocol.

Step 2: Retrieve the data from the appropriate location (eg. Oncore, REDCap, other) and produce the results needed for the primary and secondary endpoints.

Step 3: Upload/enter the results into ClinicalTrials.gov (also known as PRS). You may need to create an account on ClinicalTrials.gov and have the PI or someone in Regulatory give you access to the study to enter the results.

Step 4: Create a PDF of the results within ClinicalTrials.gov to send to the PI for them to visualize how the results will look. Meet and/or email with the PI to discuss the results and finalize the results. If there are any updates needed, update the information on ClinicalTrials.gov and email/meet with the PI again, if necessary. Once the PI approves of the results, move to Step 5.

Step 5: Submit the results on ClinicalTrials.gov. The next approval step will be from the PI, so also email the PI and Regulatory to inform them that the statistician has submitted the results for the study. This will inform the PI that they need to approve the results in ClinicalTrials.gov so the results are sent for review by ClincalTrials.gov.

Step 6: After the initial entry, ClinicalTrials.gov will perform a quality review of the information and will return queries. The results author will go back through Steps 2-5 to address the queries.

Step 7: Steps 2-6 are repeated as needed until ClinicalTrials.gov approves and releases the data to the public.

Step 8: Any further updates to the results need to be uploaded to ClinicalTrials.gov. This will involve repeating Steps 2-7 as needed. This step will possibly be needed if the results are uploaded to ClinicalTrials.gov prior to writing the main manuscript.

On the following page is a flow diagram which depicts the general process.

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┌─────────┐     ┌──────────────┐     ┌──────────────┐     ┌──────────────┐     ┌──────────────┐     ┌──────────────┐     ┌──────────────┐     ┌──────────────┐
│         │     │ Review       │     │ Retrieve     │     │ Enter initial│     │ Meet and/or  │     │ Review and   │     │ Submit       │     │ Inform PI and│
│ Study   │────▶│ Protocol for │────▶│ data and run │────▶│ results      │────▶│ Email        │────▶│ Approval     │────▶│ results on   │────▶│ Regulatory   │
│ Ends    │     │ Primary and  │     │ analysis for │     │ into         │     │ with PI to   │     │ of Results   │     │ ClinicalTrials.gov│ │ that results │
│         │     │ Secondary    │     │ Primary      │     │ ClinicalTrials.gov│ │ discuss      │     │              │     │              │     │ entry was    │
│         │     │ Objectives   │     │ and Secondary│     │              │     │ results      │     │              │     │              │     │ submitted    │
│         │     │ and confirm  │     │ Endpoints    │     │              │     │              │     │              │     │              │     │              │
│         │     │ information  │     │              │     │              │     │              │     │              │     │              │     │              │
│         │     │ on           │     │              │     │              │     │              │     │              │     │              │     │              │
│         │     │ ClinicalTrials.gov│ │              │     │              │     │              │     │              │     │              │     │              │
└─────────┘     └──────────────┘     └──────────────┘     └──────────────┘     └──────────────┘     └──────────────┘     └──────────────┘     └──────────────┘
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If updates are needed

Updates needed for Results (through queries from ClinicalTrials.gov or from updated results for manuscript)