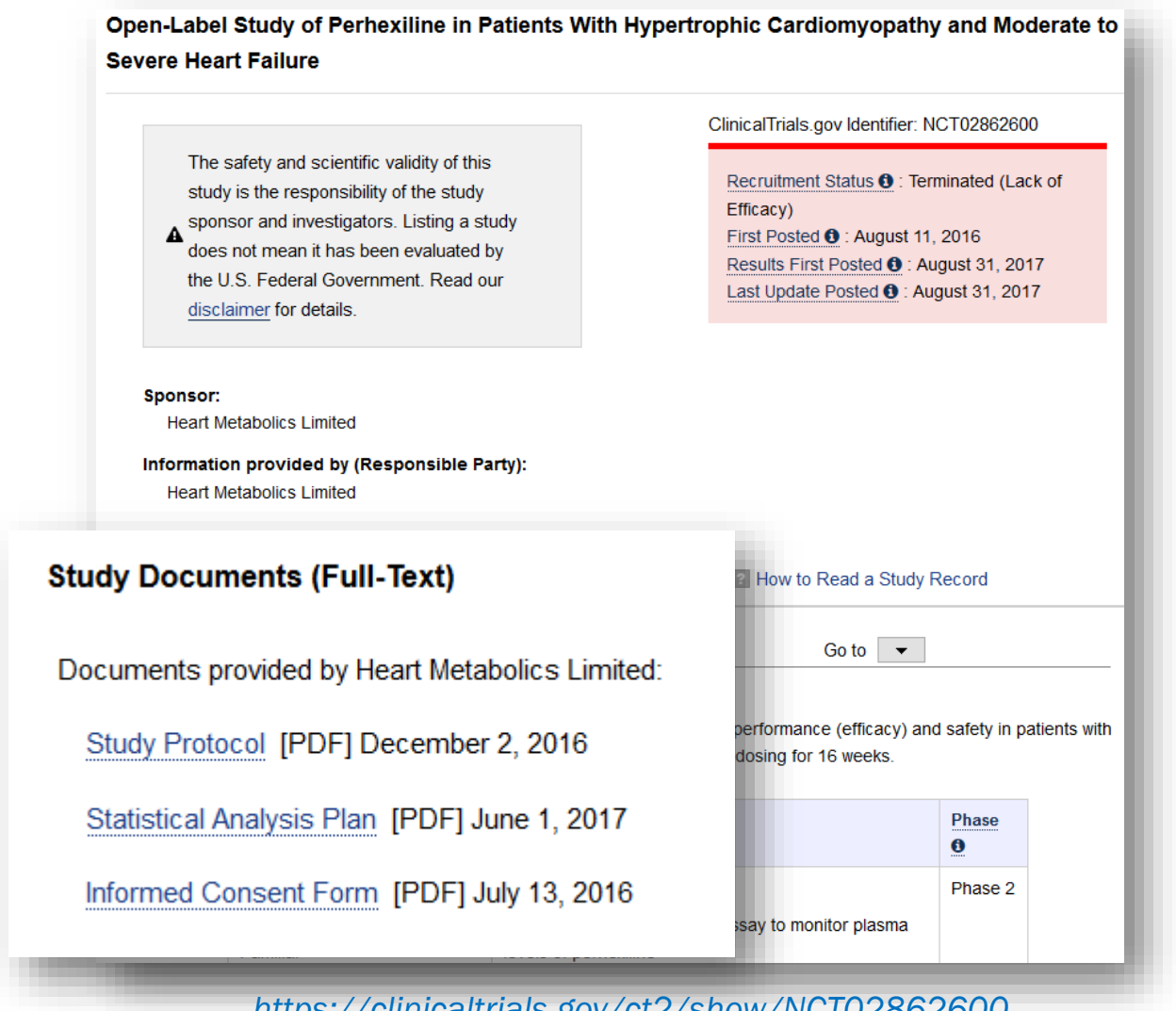
Document Upload: Introduction

Results Database Train-the-Trainer Workshop

August 2021

Study Documents

- Full Protocol and Statistical Analysis Plan (SAP) required with results information if Primary Completion Date is on or after January 18, 2017
- Revised Common Rule *requires* Informed Consent Form posting



https://clinicaltrials.gov/ct2/show/NCT02862600

Protocol and Statistical Analysis Plan (42 CFR 11.48(a)(5))

- Can be submitted as a single document (study protocol with statistical analysis plan), or as two separate documents
- Includes all amendments approved by human subjects review board (if applicable) before time of submission that apply to all locations
- Has a cover page with Official Title, NCT number, and date of document
- May redact:
  - Names, addresses, and other personally identifiable information
  - Trade secret and/or confidential commercial information (unless otherwise required to be submitted under this part)
- Is a Portable Document Format Archival (PDF/A) document
- Will be posted on ClinicalTrials.gov (made public)
- Must be in English

Informed Consent Form & Revised Common Rule (45 CFR 46.116(h))

The revised Common Rule requires that for any clinical trial conducted or supported by a Common Rule department or agency, one consent form be posted on a publicly available federal website within a specific time frame

Federal websites that may be used to satisfy the requirement:

- ClinicalTrials.gov (for registered clinical trials)
- Regulations.gov (Docket ID: HHS-OPHS-2018-0021)

The compliance date for this provision is January 21, 2019