

# 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

## Open-Label Study of Perhexiline in Patients With Hypertrophic Cardiomyopathy and Moderate to Severe Heart Failure

ClinicalTrials.gov Identifier: NCT02862600

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

**Recruitment Status** ⓘ : Terminated (Lack of Efficacy)

**First Posted** ⓘ : August 11, 2016

**Results First Posted** ⓘ : August 31, 2017

**Last Update Posted** ⓘ : August 31, 2017

### Sponsor:

Heart Metabolics Limited

### Information provided by (Responsible Party):

Heart Metabolics Limited

## Study Documents (Full-Text)

Documents provided by Heart Metabolics Limited:

[Study Protocol](#) [PDF] December 2, 2016

[Statistical Analysis Plan](#) [PDF] June 1, 2017

[Informed Consent Form](#) [PDF] July 13, 2016

How to Read a Study Record

Go to

performance (efficacy) and safety in patients with dosing for 16 weeks.

	Phase
	Phase 2

assay to monitor plasma

<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](https://clinicaltrials.gov) (for registered clinical trials)
- [Regulations.gov](https://www.regulations.gov) (Docket ID: HHS-OPHS-2018-0021)

The compliance date for this provision is January 21, 2019