DATA MANAGEMENT PLAN

e-DETECT

1. GENERAL INFORMATION

Project title: **e**arly **Det**ection of dis**e**ase in ***c***ardiomyopa**t**hy mutation carriers - *e*-DETECT

1) Contact person of the project? Provide contact details (full name, institute, e-mail address and telephone number)

Full name	**Institute**	**E-mail address**	**Telephone number**
J. Peter van Tintelen	UMC Utrecht	j.p.vantintelen-2@umcutrecht.nl	+31(0)88 7553810

2) Who is responsible for data management in this project?

Full name	**Institute**	**E-mail address**	**Telephone number**
Erik van Iperen	Netherlands Heart institute	e.p.vaniperen@amc.uva.nl	+31(0)205666502

3) Is there a back-up data manager?

Full name	**Institute**	**E-mail address**	**Telephone number**
Wanda van Ast	Netherlands Heart institute	wanda.hermans-vanast@durrercenter.nl	+310205666499

2. THIRD-PARTY DATA REUSE

1) Did the researchers search for third-party data that could be reused in the current project?

Yes.
Relevant data has been identified for reuse. In WP2, participants with a PLN and/or PKP2 mutation who are included in the UNRAVEL, iPHORECAST or the NLHI ACM registry, will be included in eDETECT WP2.

2) Is the informed consent form applicable for reuse of third-party data?

Yes. Participants of UNRAVEL and ACM have been informed about potential reuse of the data.

3. CREATING AND PROCESSING DATA

1) Will the authors use metadata standards that can be used in the project? Include a description, if applicable.

Yes.
This question should be updated once a consent regarding standards is achieved. Snomed and ICD10 codes will be used. Also, items formulated according to the Clinical data Acquisition Standards Harmonization (CDASH) were also used to build the electronic case report forms. Furthermore, the study will be described using MIABIS (for the BBMRI-NL catalogue) which also makes use of the NCI thesaurus standard. Moreover, the data will also be described using the Maelstrom Research Areas of Information terminology.

The questionnaires used in WP1 are based on metadata standards (TMSI, OCDF and STAI).

2) List all the variables that will be measured in the study. Specify which tools/instruments will be used for measuring the data.

e-DETECT is divided across different workpackages. For sake of completeness, we will describe the variables across the different work packages (WPs).
WP1: Qualitative Data
"Informing relatives at risk of inherited cardaic diseases: a qualitative study with health care professionals, patients and relatives."

A. Instrument: Interviews patients and family members
   Domains: Own experience, informing family members; Actual vs. Active way of informing family members; Informing family members as an obligation or responsibility; Right of not knowing; Mean for transfering the information; Type of information; Terms and conditions for notification of hereditary advice; Providing information.

B. Instrument: Focus groups with caregivers
   Domains: Ways to contact family members, Responsibilities to inform family members; Direct/active way; Information for family members; Conditions / barriers to applying hereditary advice.

Used standards/data:
Quantitative data: questionnaires are listed, all items included if not otherwise specified.
Motivational to inform family members: Informing Relatives inventory (IRI)
Family communication style: Adaped version of the questionnaire "Opennes to Discuss Hereditary Cancer in the Family" (OCDF)
All items of the "Threatening Medical Situations Inventory" (TMSI)
Trait subscale of the State Trait Anxiety Inventory (STAI)

WP2: The data dictionary for this work package is available upon request and will be provided by the datamanager. Regarding areas of information that were used: demographics, presentation, family history, exercise history, medication, ECG, saECG, Holter, exercise tolerance test, physiology, MRI, echocardiogram, angiogram, tissue biopsy, arrhythmic events ICD, inappropriate ICD intervention, atrial arrhythmia, pregnancy, heart failure, htx, death, diagnostic tfc. When available and applicable, classification of the AHA or ESC are used.

WP3: PICP, PINP, PIIINP and ICTP (peptides involved in collagen synthesis/turnover). miRNAs (miRNA-21, 30c and 133a). Sodium current reduction, characteristics of impulse propagation. Sodium current and action potential (AP) characteristics in iPSC-CM.

3) What will be the procedure to standardize metadata for variables without standard ontologies?

New metadata standards will be published at biosharing.org. We will discuss which standards might be interesting to publish. Work package leaders will be contacted for it at a later stage of the project.

4. DATA COLLECTION AND IT PROFESSIONALISM

1) How will existing third-party data be combined with new data?

When applicable, the approach described by Rolland et al. (2013) will be used for harmonizing data. In WP2, the eCRF software REDCap will be used. This software allows multi-center data entry.

2) How are data edits going to be documented?

Electronic case report forms (eCRFs) built with REDCap will be used across all centers involved for entering data. Logs for data edits will be extracted from REDCap.

3) Is the data going to be audited/monitored?

Yes.

4) Will you apply strategies to prevent data entry mistakes? If so, describe.

Yes.
Validation rules will be used when applicable and computed using REDCap.

5) How is the data going to be stored, integrated and backed-up during the data collection phase?

Pseudonymized data will be stored and backed-up at the private server of the Netherlands Heart Institute (hosted at transIP). Images will be stored at the CTMM-TraIT server using the BioMedical Imaging Archive (hosted by Vancis). The following storage space is estimated:

- Size MRI scans: 135 GB
- Size echo studies: 414 GB
- Size ECGs: 400 MB
- Ajmaline tests: 50 MB

Data from WP3 will be stored at the local servers of the Academic Medical Center (AMC) and of the University Medical Center Utrecht (UMCU).
A document displaying the data architecture workflow is under development and will be available upon request.

5. PRIVACY AND INTEGRITY

1) Will the project need approval by a medical ethical committee?

Yes.
Ethical approval is needed for the active approach in WP1, and clinical investigations in WP2. A request for ethical approval to collect buccal mucosa samples has recently been submitted. Approval by the medical ethical committee of the UMCU has already been given.

2) Will informed consent be asked to the study participants? Describe the procedure that will be used to obtain informed consent of the participants.

Yes.
Informed consent forms will be stored at the local UMCs collecting data (in archives, for paper version), and on a secure database for digital version.

3) Is there a committee assigned to review privacy and integrity issues of the project?

Yes.
The Research Data Management platforms of the three participating UMCs offer solutions for reviewing privacy and integrity issues and will be contacted for providing this assistance when needed.

6. BUDGET

1) How are costs for data management going to be covered in the project?

The budget used for WP4 Data management is applicable for all related data management issues.