Plan Overview

A Data Management Plan created using DMPonline

Title: A Global Post Market Evaluation of Terumo Aortic Endovascular Grafts (TIGER Registry)

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Template: UMC Utrecht DMP

Project abstract:

Multi-arm, multi-center, open label, prospective observational registry designed to obtain safety and performance data on the use of CE marked and custom Terumo Aortic endovascular grafts. In this registry we shall collect real world, post-approval safety, performance, patient reported outcomes and health economic data on patients treated with Terumo Aortic endovascular stent-grafts in standard clinical practice.

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End date: 01-11-2030

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Copyright information:

A Global Post Market Evaluation of Terumo Aortic Endovascular Grafts (TIGER Registry)

1. General features

1.1. Please fill in the table below. When not applicable (yet), please fill in N/A.

DMP template version	29 (don't change)
ABR number *(only for human-related research)*	
METC number *(only for human-related research)*	TBD
DEC number *(only for animal-related research)*	
Acronym/short study title	TiGER
Name Research Folder	xx-xxx_TiGER
Name Division	Surgical Specialties
Name Department	Vascular Surgery
Partner Organization	Vascutek Ltd, Bolton Medical
Start date study	15-11-2023
Planned end date study	15-11-2033
Name of datamanager consulted*	Dax Steins & Nivard Koning
Check date by datamanager	8-9-2023

1.2 Select the specifics that are applicable for your research.

- Clinical study
- Multicenter study
- Prospective study
- Non-WMO
- Observational study

This study is a multi-arm, multi-center, open label, prospective observational registry involving standard of care designed to obtain safety and performance data on the use of CE marked and custom Terumo Aortic endovascular grafts. A minimum of 45 sites globally. Where a site is actively participating in the TREO Registry (IP-0020-16). Participants will be invited to have their data migrated from TREO to the TiGER registry.

All Commercial Terumo Aortic* Endovascular Grafts are eligible for inclusion within this registry. As new Terumo Aortic endovascular devices become commercially available they will also be eligible for inclusion into the registry

2. Data Collection

2.1 Give a short description of the research data.

This multi-arm, multi-centre, open label, prospective observational registry of all Terumo Aortic endovascular grafts is part of Terumo Aortics Post Market Clinical Follow-up plan and will provide insight into both the short and long term clinical outcomes of all marketed and custom devices. The effect of endovascular aneurysm/aortic repair (i.e. EVAR, FEVAR and TEVAR) on post-operative patient reported health outcomes will be assessed retrospectively. In addition this registry will provide long-term data on device performance in a real world population.

This observational registry is designed to obtain safety and performance data on the use of CE marked and custom Terumo Aortic endovascular grafts. Different sites will be selected to provide a range of user experience, with both high and low volume. There is no minimum or maximum enrolment requirement. Because this registry is non-interventional, only patients who would normally receive treatment with a Terumo Aortic device as part of standard treatment at the participating institute can be enrolled.

This registry has a minimim follow-up periode of at least 1 year as per standard of care.

Primary endpoint: Aortic related Mortality.

Additional Endpoints:

1. All-cause Mortality
2. Composite technical success defined as:
    - Successful delivery of the device through the vasculature (i.e. ability to deliver the implant to the intended location without the need for unanticipated corrective intervention related to delivery)
    - Deployment of the endovascular stent graft in the planned location with coverage of the target lesion;
    - Patency of the endovascular stent graft, absence of device deformations (e.g. kinks, stent eversion, mal-deployment, misaligned deployment) requiring unplanned placement of an additional device within the endovascular stent graft, and;
    - Successful withdrawal (i.e. successful withdrawal of the delivery system, without the need for unanticipated corrective intervention related to withdrawal)
    - Absence of type I and type III endoleak
3. Composite clinical success defined as the absence of:
    - Target lesion related mortality
    - Target lesion aortic rupture
    - Target lesion reintervention
    - Occurrence of Endoleaks (Type Ia, Ib, III and IV)
    - Loss of stent patency (>50%)
    - Clinically significant stent graft migration (≥10mm)
    - Stent fracture
    - Stroke (an mRS score of 2 or more at 90 days and an increase in at least one mRS category from an individual's pre-stroke baseline)
    - New onset renal failure requiring dialysis
    - Graft infection or thrombosis
    - Where aneurysm is present
        - Aneurysm expansion (diameter ≥5 mm, or volume ≥5%)
4. Patient outcome measures
    - Post-operative return to normal activities – employment, household activities, social life and hobbies (return to normal activities will be recorded at one year visit only)
5. Health Economic Parameters
    - Total procedure time
    - Arterial access route and type
    - Volume of contrast media used
    - Fluoroscopy time
    - Image fusion technology used
    - Magnet system used
    - Device re-positioned
    - Blood loss
    - Blood transfusion required
    - Lower limb ischemia
    - Time in ICU/MCUb
    - Time to hospital dischargec
    - Complications requiring reintervention/re-hospitalisation

Pseudonymized data, this includes processed imaging data, will be collected at the following time points:
• Baseline - Procedure
• Early follow-up (discharge/30 days to six months)
• One-year post index procedure
• Mid- to long-term follow-up up to 10 years post index procedure

Subjects	Volume	Data Source	Data Capture Tool	File Type	Format	Storage space
Human	>1000	EPD (HiX)	eCRF	Quantitative		0-10 GB
Human	>1000	eCRF	iMedNet	Quantitative		0-10 GB
Human			PACS	Images		

*Where an event (Device related or possibly device related) occurs, imaging analysis may be further reviewed by a third-party reader (Core Lab) for investigation.

2.2 Do you reuse existing data?

- No, please specify

TiGER registry is initiated by Terumo to collect real world, post-approval safety, performance, patient reported outcomes and health economic data on patients treated with Terumo Aortic endovascular stent-grafts in **standard clinical practice**.

2.3 Describe who will have access to which data during your study.

Type of data	Who has access
Direct identifying personal data	Research team with care relationship to patient, Datamanager
Key table linking study specific IDs to Patient IDs	PI (with care relationship to patient), Datamanager
Pseudonymized data	Research team, Datamanager

2.4 Describe how you will take care of good data quality.

Experimental data from patients will be collected in an electronic Case Report Form (eCRF) in a certified Data Capture Tool: iMednet provided by the Sponsor. In the eCRF, skips and validation checks are built in. Data quality will be checked by an independent monitor from the sponsor.

#	Question	Yes	No	N/A
1.	Do you use a certified Data Capture Tool or Electronic Lab Notebook?	X		
2.	Have you built in skips and validation checks?	X		
3.	Do you perform repeated measurements?		X	
4.	Are your devices calibrated?			X
5.	Are your data (partially) checked by others (4 eyes principle)?	X		
6.	Are your data fully up to date?	X		
7.	Do you lock your raw data (frozen dataset)			
8.	Do you keep a logging (audit trail) of all changes?	X		
9.	Do you have a policy for handling missing data?	X		
10.	Do you have a policy for handling outliers?	X		

2.5 Specify data management costs and how you plan to cover these costs.

#	Type of costs	Division ("overhead")	Funder	Other (specify)
1.	Time of datamanager		X	
2.	Design of eCRF		X	
3.	Data Capture Tool license fee		X	
4.	Questionnaire license fee		X	
5.	Storage		X	
6.	Archiving		X	

2.6 State how ownership of the data and intellectual property rights (IPR) to the data will be managed, and which agreements will be or are made.

According to the Post-Market study agreement the UMC assigns to Vascutek all existing and future Intellectual Property Rights in the Study Data / Data and/or any all materials embodying these rights to the fullest extent permitted by law. Insofar as they do not vest automatically by operation of law or under this agreement, the Institution and/or the Principal Investigator holds legal title in these rights and inventions on trust for Vascutek.

3. Personal data (Data Protection Impact Assessment (DPIA) light)

Will you be using personal data (direct or indirect identifying) from the Electronic Patient Dossier (EPD), DNA, body material, images or any other form of personal data?

- Yes, go to next question

I will process personal data. I have checked the full DPIA checklist and I do not have to complete a full DPIA. I therefore fill out this

DPIA light and proceed to 3.1.

3.1 Describe which personal data you are collecting and why you need them.

Which personal data?	Why?
Pre-Procedure: Medical history (Date of birth, Sex, Race, Height, Weight, patient medical history, ASA class)	Describe study population and assess possible risks
Pre-Procedure, Early follow-up, 1 year and 2-10 years: Vital signs & eGFR	Describe study population and assess possible risks
Pre-Procedure: device selection (Aortic pathology & Indication)	Describe study population and assess possible risks
Pre-Procedure: Baseline Imaging thoracic, Baseline Imaging AAA, Pre-Operative activities (Date of imaging performed, Imaging techniques, lesion measurement, calcification & tortuosity & access site minimum of access artery	describe study primary and secondary endpoints
Procedure information: implant (hospital admission, procedure information (date, time, contrastvolume etc.), access site, devices used, presence of endoleak	describe study primary and secondary endpoints
Device Assessment: implant	describe study primary and secondary endpoints
Discharge: implant (discharge date, post procedure hours in ICU, discharge destination)	describe study primary and secondary endpoints
Follow-up: Early follo-up, 1 year, 2-10 years (safety evaluation, imaging performed, vessel patency,	describe study primary and secondary endpoints

3.2 What legal right do you have to process personal data?

- Study-specific informed consent

3.3 Describe how you manage your data to comply to the rights of study participants.

The data are pseudonymized and the linking table to personal data is saved. An authorized person manages the linking table, can re-identify study participants when necessary and deliver, correct or delete the data. The procedure can be found: <storage location>

Right	Example answers
Right of Access	Research data are coded, but can be linked back to personal data, so we can generate a personal record at the moment the person requires that. This needs to be done by an authorized person.
Right of Access	We have to refuse participant's right of access, because this would make the research impossible to conduct given the large number of participants (n=1000).
Right of Rectification	The authorized person will give the code for which data have to be rectified.
Right of Objection	We use informed consents.
Right to be Forgotten	In the informed consent we state that the study participant can stop taking part in the research. Removal of collected data from the research database cannot be granted because this would result in a research bias.

3.4 Describe the tools and procedures that you use to ensure that only authorized persons have access to personal data.

1. We use the secured Research Folder Structure that ensures that only authorized personnel has access to personal data, including the key table that links personal data to the pseudoID.
2. We make use of a certified Electronic Data Capture (EDC) tool provided by sponsor and created by a CRO.

3.5 Describe how you ensure secure transport of personal data and what contracts are in place for doing that.

We have a Post-Market study agreement with Vascutek. The agreement is stored at location: *L:|Onderzoek|Vaatchirurgie|xx-xxx_TIGER|B_Documentation|6_Contracts*

4. Data Storage and Backup

4.1 Describe where you will store your data and documentation during the research.

The digital files will be stored in the secured Research Folder Structure of the UMC Utrecht. We will need +/- 50 GB storage space, so the capacity of the network drive will be sufficient. Paper dossiers will be stored safely in a locked cabinet in a locked room in the UMC Utrecht. A project specific procedure is in place for access to the paper dossiers. Documentation of this procedure is stored in the Research Folder Structure.

4.2 Describe your backup strategy or the automated backup strategy of your storage locations.

1. All (research) data is stored on UMC Utrecht networked drives from which backups are made automatically twice a day by the division IT (dIT).
2. During data collection, automatic backups will be made in the Electronic Data Capture Tool.

5. Metadata and Documentation

5.1 Describe the metadata that you will collect and which standards you use.

For the data collected in EDC, sponsor defined standards.

5.2 Describe your version control and file naming standards.

We will distinguish versions by indicating the version in the filename of the master copy by adding a code after each edit, for example V1.1 (first number for major versions, last for minor versions). The most recent copy at the master location is always used as the source, and before any editing, this file is saved with the new version code in the filename. The file with the highest code number is the most recent version. Every month, we will move minor versions to a folder OLD. The major versions will be listed in a version document (projxVersDoc.txt), stating the distinguishing elements per listed version.

6. Data Analysis

6 Describe how you will make the data analysis procedure insightful for peers.

Data is processed and analyzed by sponsor. Not applicable within UMC Utrecht.

7. Data Preservation and Archiving

7.1 Describe which data and documents are needed to reproduce your findings.

The data package will contain: the raw data, the study protocol describing the methods and materials, the script to process the data, the scripts leading to tables and figures in the publication, a codebook with explanations on the variable names, and a 'read_me.txt' file with an overview of files included and their content and use.

7.2 Describe for how long the data and documents needed for reproducibility will be available.

After end of study, data must be stored for at least 2 years by the participating center and at least 5 years by the sponsor.

7.3 Describe which archive or repository (include the link!) you will use for long-term archiving of your data and whether the repository is certified.

After finishing the project, the data package will be stored at the UMC Utrecht Research Folder Structure and is under the responsibility of the Principal Investigator of the research group.

7.4 Give the Persistent Identifier (PID) that you will use as a permanent link to your published dataset.

The data that are used in publication XXX are published with the publication and are to be found under the PID XXX.

** I will update 'XXX' in this answer when available.*

8. Data Sharing Statement

8.1 Describe what reuse of your research data you intend or foresee, and what audience will be interested in your data.

Study specific Post market surveillance of Vascutek. Data is collected and processed by vascutek.

8.2 Are there any reasons to make part of the data NOT publicly available or to restrict access to the data once made publicly available?

- Yes (please specify)
- The Institution and the Principal Investigator hereby agrees and undertakes that no Data shall be made publically available by such means as (but not limited to) peer review, presentations or other forms of publication unless:
    - the Institution and the Principal Investigator has obtained the written consent of the Clinical Trial or Study Publication Committee;
    - the Data has been fully anonymised; and
    - such publication or presentation complies with the Publication Policy detailed in the CIP or Study Protocol, as the same may be amended from time to time.

8.3 Describe which metadata will be available with the data and what methods or software tools are needed to reuse the data.

- The Institution and the Principal Investigator hereby agrees and undertakes that no Data shall be made publically available by such means as (but not limited to) peer review, presentations or other forms of publication unless:

    - the Institution and the Principal Investigator has obtained the written consent of the Clinical Trial or Study Publication Committee;
    - the Data has been fully anonymised; and
    - such publication or presentation complies with the Publication Policy detailed in the CIP or Study Protocol, as the same may be amended from time to time.

8.4 Describe when and for how long the (meta)data will be available for reuse

- Other (please specify)

UMC Utrecht is only participating in Research. Vascutek collects all studyinformation and is owner of the database.

8.5 Describe where you will make your data findable and available to others.

- The Institution and the Principal Investigator hereby agrees and undertakes that no Data shall be made publically available by such means as (but not limited to) peer review, presentations or other forms of publication unless:
    - the Institution and the Principal Investigator has obtained the written consent of the Clinical Trial or Study Publication Committee;
    - the Data has been fully anonymised; and
    - such publication or presentation complies with the Publication Policy detailed in the CIP or Study Protocol, as the same may be amended from time to time.