Plan Overview

A Data Management Plan created using DMPonline

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CAPRI-3

Data Collection

What data will you collect or create?

- Baseline patient characteristics (including year of birth, comorbidity, prostate cancer histology, androgen deprivation therapy);
- Patient parameters during metastatic HSPC and CRPC (including clinical parameters (WHO performance status, opioid use, weight), laboratory parameters (including haemoglobin, lactate dehydrogenase, alkaline phosphatase, PSA, albumin, NLR, etc.), and extent of disease);
- Next generation sequencing data;
- Biochemical response (PSA, ALP);
- Serious adverse events (SAE), limited to hospitalization and death;
- Use of systemic treatments (including, but not limited to, docetaxel, cabazitaxel, mitoxantrone, abiraterone, enzalutamide, radium-223, olaparib, apalutamide, Lu-PSMA (number of cycles, start and stop date, reason of discontinuation);
- Use of supportive care (including radiotherapy and radionuclides);
- Resource use (including hospital admissions);
- Referral patterns and use of multidisciplinary treatment consultations.

How will the data be collected or created?

Patient identification and data collection will mainly take place in CTcue: a web-based software tool (linked to the local electronic patient record system) that offers easy identification, validation and collection of pseudonymized data. Then, data is exported to Castor EDC for manual completion and storage of the data.

First, the coordinating investigator will import the CTcue algorithm from the investigator site to the participating hospital using the CTcue Hub. The study criteria and data points will be amended to fit the participating hospital and manually checked for errors. Once CTcue is adequately prepared, patients will be automatically identified with CTcue's Patient Finder using bulk criteria for inclusion (such as specific DBC codes).
Trained datamanagers will manually check each automatically included subject and go through the remaining group of patients to check for eligibility.
After informed consent, datamanagers will validate part of the data (i.e. data of less quality) using CTcue’s Clinical Data Collector. The validated data together with the readily available data (such as lab values) will be exported from CTcue into Castor EDC by the coordinating investigator. Finally, the datamanagers will complete the records in Castor EDC by inspecting the EPR. All actions in Castor will be logged.

CTcue only allows access when logged into the hospital environment. Export rights (downloading data files from CTcue onto the local disk) are reserved for investigators; datamanagers do not have these rights. Naming and storing of data files is standardized. The data files will be locked twice a year. Data completion in Castor will continue as long as follow-up is indicated.

Documentation and Metadata

What documentation and metadata will accompany the data?

In Castor all actions will be logged: who created or contributed to the data, its title, date of creation and under what conditions it can be accessed.

Information on interpretation of data is stored digitally. This includes documentation of methodology (CAPRI3 protocol), definitions of the variables and instructions how to collect the data (datamanager instruction document), units of measurement (empty CRF) and analytical information (such as SPSS syntaxes).
The documents are accessible to the datamanagers and the board members of the CAPRI foundation.

Ethics and Legal Compliance

How will you manage any ethical issues?

Patients who are still under treatment of the participating hospital will be asked for written informed consent prior to inclusion in the study by their treating physician.
Necessary up-to-date information from patients who are no longer under treatment, such as current home address and whether a person is alive or deceased, aren't readily available. Therefore, patients who are no longer under treatment of the participating hospital, can be enrolled without written informed consent.
Patients that have died prior to first identification and are thus not able to provide written informed consent are included automatically.

After identification of eligible patients by the CTcue software package and after written informed consent from aforementioned patients, data are pseudonymized and will be validated by trained datamanagers using CTcue's Clinical Data Collector.

Data will be exported by the coordinating investigator to a web-based eCRF compliant with Dutch and European privacy guidelines. Data will be stored on the Digital Research Environment of Radboudumc using Castor (Castor Research, Inc.) according to Dutch laws.

Data will be handled with uppermost caution and all datamanagers will sign a non-disclosure agreement. Furthermore, no direct identifying data will be registered in the eCRF and a code will be used to prevent tracing back data to an identifiable patient. The key of the code will be stored in the participating hospitals.

How will you manage copyright and Intellectual Property Rights (IPR) issues?

To conclude agreements and concracts with partners and stakeholders, a central legal entity (the CAPRI foundation) was formed. Focus areas of the foundation include solving issues regarding data ownership (e.g. raw data, processed data).

The raw data is made available by the participating hospitals to the CAPRI study according to the data processing agreements. The participating hospitals remain the owners of the raw data and may use their own raw data and analyses.

All other research and data processing by CAPRI or other stakeholders needs approval from the scientific committee of the CAPRI foundation. Data collection, transmission or storage does not imply a tacit consent of the scientific committee.

It is under no condition permitted to sell data from reports.

Storage and Backup

How will the data be stored and backed up during the research?

Data collection files will be downloaded from CTcue onto the local disk (research folder) of the participating hospitals. Access is limited to the local and coordinating investigators and datamanagers.
Paper documents (informed consent forms) will be stored at the participating hospital in locked storage units.
Only no-direct identifying data will be uploaded and stored on the Digital Research Environment of Radboudumc using Castor (Castor Research, Inc.).

All abovementioned data can only be accessed by authorized personnel.

How will you manage access and security?

The local principal investigator and datamanager will be authorized to access the local research disk.
The datamanager will also have access to CTcue and Castor to validate and complete the data.
Datamanagers will have limited rights and all actions in Castor will be logged and checked regularly.

Selection and Preservation

Which data are of long-term value and should be retained, shared, and/or preserved?

Raw (direct identifying) data, including downloaded data files from CTcue and informed consent forms, have no use in future research and will be destroyed after 15 years.
Stored (no direct identifying) data on Castor are of long-term value and will be preserved. The main research purpose of long-term preservation of data is cross-comparison with future cohorts.

What is the long-term preservation plan for the dataset?

The CAPRI foundation will fund the long-term preservation of the dataset in Castor, as long as the data is valuable for research purposes. The estimated cost is 375-750 euro per year (depending on continious enrollment of subjects into Castor).

Data Sharing

How will you share the data?

The participating hospitals will share raw data with CAPRI. As mentioned before, only no direct identifying data will be uploaded onto Castor. This pseudonymized raw data will not be shared with any third parties. Only analyzed results will be published and/or shared with stakeholders.

Are any restrictions on data sharing required?

The raw data is made available by the participating hospitals to the CAPRI study according to the data sharing agreements (DTA).
See chapter 'ethical and legal compliance'.

Responsibilities and Resources

Who will be responsible for data management?

The coordinating investigator is responsible for data management (including data capture, metadata production, data quality, storage and backup), but will delegate datacollection tasks to trained datamanagers across participating hospitals. Datamanagers work under indirect supervision of the coordinating investigator.
Data archiving will be handled by employees of the participating hospitals and is the responsibility of the local principal investigator.

What resources will you require to deliver your plan?

- CTcue software and support
- Castor
- Datamanagers