Project Charter

Template v2 June 3, 2015

Name of Project: **Prostate Cancer (PrCa) Therapeutic Area Data Standards** February 25, 2016

Project Manager: **John Owen**

1. Scope of Prostate Cancer Therapeutic Area Project

1.1. Project Description

The Prostate Cancer therapeutic area standards project is being performed under the CFAST initiative to accelerate clinical research and medical product development by facilitating the creation and maintenance of data standards, tools, and methods for conducting research in therapeutic areas important to public health.

The Prostate Cancer Project will collaborate with the SHARE team to develop Biomedical Concepts and untilze the SHARE ecosystem tools available in the development of the PrCa TAUG. This will form a template for the development of future TAUG's.

Biomedical Concept spreadsheets for Lab Tests, Pathology Tests and QRS Instruments will be developed and included in the SHARE metadata repository. Templates exist for Lab Tests and QRS Intruments, however, a Biomedical Concept spreadsheet template will be developed for Pathology Tests.

1.2. Disease Characteristics

> 90% prostate cancer cases occur in men over the age of 50. Symptoms of prostate cancer in later stages can include difficulty urinating, blood present in the urine and pelvic pain when urinating.

1.3. Type of Studies

The project scope will include Phase 1 through Phase 4 clinical trials.

1.4. Focus Population

This project pertains to treating male adults with Prostate Cancer.

1.5. Specific Indications

This project will focus on concepts to advanced prostate cancer with a focus on

- Castrate Resistant Prostate Cancer (CPRC)
- Metastatic Prostate Cancer

1.6. Proposed Scope

The project is scoped to achieve its deliverables within a time frame of 10 months as agreed by CFAST.
The PrCa project is an FDA grant-funded project and these timelines have been communicated to the FDA PrCa representatives.

Those rows highlighted in yellow are concepts where Biomedical Concept Spreadsheet data will be created for loading into the SHARE Ecosystem

Type of Data	Magnitude	Gap Analysis
Disease History	**Low-Medium** – Will develop concepts specific to prostate cancer disease history utilizing those that have already been developed for the Breast Cancer project.	• No new domains or variables expected. • Development will focus on examples of how to represent Disease History data utilizing existing standards. • Potential for additional Controlled Terminology pending investigation during stage 1. • Associated domains: MH
Radiation Treatment History	**Low** – Expected to make use of the concepts developed in the Breast Cancer Project.	• No new domains or variables expected. • Development will focus on examples of how to represent radiation treatment history data utilizing existing standards. • Potential for additional Controlled Terminology pending investigation during stage 1. • Associated domains: PR
Medication Treatment History	**Low - Medium** - Expected to make use of the concepts developed in the Breast Cancer Project with additional development of CDASH CRF's for prior antineoplastic therapy, and infusion drugs (both as concomitant/prior medication and as study treatment).	• No new domains or variables expected. • Development will focus on examples of how to represent medication treatment history data utilizing existing standards. • Potential for additional Controlled Terminology pending investigation during stage 1. • Development of CDASH CRF's to collect medication treatment history data. • Associated domains: CM
Surgical Treatment History	**Low** - Expected to make use of the concepts developed in the Breast Cancer Project	• No new domains or variables expected. • Development will focus on examples of how to represent surgical treatment history data utilizing existing standards. • Potential for additional Controlled Terminology

Type of Data	Magnitude	Gap Analysis
		pending investigation during stage 1. • Associated domains: PR
Pathology/Lab tests	**High** – 23 Prostate Cancer Specific Pathology/lab concepts will be developed. The TAUG will focus on example development on how to represent this data in SDTM	• Development of Pathology biomedical concept spreadsheet template. • No new domains or variables expected. • Development will focus on examples of how to represent pathology/lab test data utilizing existing standards. • Additional Controlled Terminology will be pending investigation during stage 1. • Associated domains: LB
Assessment of bone lesions per PCWG2	**Medium** – Bone involvement is an important concept in advanced prostate cancer since spread of the disease often involves lesions in the bone.	• No new domains or variables expected. • SDTM Modeling will be investigated further during concept development with potential alignment of the modeling with that for RECIST. • Potential for additional Controlled Terminology pending investigation during stage 1 • Associated domains: TU/TR/RS
RECIST	**Low** - Already covered as a concept in breast cancer. We will be evaluating any specifics that need highlighting for prostate cancer during the concept development phase	• Covered in existing TU/TR/RS domains. • Potential for additional Controlled Terminology pending investigation during stage 1 • Associated domains: TU/TR/RS
Skeletal Related Events	**Medium** – Focus will be on the development of CDASH complaint CRF's	• No new domains or variables expected. • Radiotherapy to bone metastases would be recorded in PR • Surgery to bone metastases would be recorded in PR • Pathologic bone fracture would be recorded in AE or CE • Spinal cord compression would be recorded in AE or CE • Potential for additional Controlled Terminology pending investigation during

Type of Data	Magnitude	Gap Analysis
		stage 1 • Associated domains: CE
QRS	**High** - 15 scales identified during scoping. Endpoints using QRS instruments are important especially in advanced prostate cancer where bone/pain involvement is assessed.	• Gap analysis still ongoing with team members who are QRS specialists • Anticipating having to develop metadata for 9 out of 15 scales (the others already have supplements created) • Development would follow the existing QRS defined process. • Review of the Pain TAUG to be done. • Associated domains: QS

1.7. Project Deliverables

Therapeutic Area Standards User Guide (TAUG) that will include:

- Essential core biomedical concepts with definitions, data types (simple & ISO 21090) and SDTM mappings
- Concept maps of disease area research concepts
- CDASH metadata for selected research concepts
- Selected annotated CRFs (with CDASH and SDTM-based annotations)
- SDTM examples, as appropriate
- Minimum terminology value sets (code lists) with definitions and C-Codes, as appropriate
- Inclusion of analysis guidelines will continue to be evaluated by the project team. If deemed appropriate and resource is available, may include the following:
    - Identification of the data needed for endpoint derivations, but not the actual statistical analyses of endpoints.
    - Description of how the clinical endpoints translate into statistical endpoints.
    - Examples of ADaM compliant analysis datasets.
    - Selected example table shells/figures and illustrations (via analysis results metadata) of the crosswalk from the ADaM dataset(s) to the analysis.

Project deliverables will reference sources and describe provenance used in their creation.

1.8. Project Milestones

The project will follow the enhanced therapeutic area standards development process.
High-level project plan:

Project Stage	Project Stage Description	Timeline (End)
Stage 0	Scoping & Planning	October 2015
Stage 1	Concept Modeling	February 2016
Stage 2	Standards Development	April 2016
Stage 3a	Internal Review	May 2016
Stage 3b	Public Review	July 2016
Stage 3c	Publication	August 2016

More detailed dates and milestones will be maintained in a separate project plan on the CDISC portal.

1.9. Complexity Assessment: (Gaps, Risks, Complexities and Challenges)

• Major potential risks:

- For this project to succeed, assigned resources must continue be made available to work on project deliverables. It is critical that personnel assigned are able to prioritize the project above other responsibilities regardless of the organization providing the resource.
- In order to provide the required deliverables within the agreed timeframe in the FDA Grant Award, this project will rely on close collaboration with the SHARE team.

• Project Complexity:

- **Medium Complexity** – based on initial assessment of the Prostate Cancer concepts and experience with the first oncology Indication (Breast Cancer) most development will be focused on Non-standard variables to support existing domains and variables, as well as development of controlled terminology.

• Significant Project Challenges:

- Prostate Cancer will be the first TA to incorporate the SHARE ecosystem and SHARE team into the development process there will be additional focus on the TAUG development process as the CFAST team and the SHARE team will develop a template process for future TAUG's to follow.

1.10. Project Document Repository

Project documents will be maintained in the CDISC portal under Teams Projects > Therapeutic Disease Specialty > Prostate Cancer and will be accessible to all team members.

1.11. Plans for Future Versions

Biomedical Concepts will be developed for Lab Tests, Pathology Tests and QRS Instruments. These will be prioritized in order of importance and may result in additional development work being performed for later versions of the TAUG. This is dependent on time and resource availability.

2. Resources

2.1. Team Members

Project Team members fall into five roles with different responsibilities. Members in project level roles are recruited for the particular therapeutic area project. Not listed below are program level resources that support all TA projects. Reviewers are not listed as these evolve over the life of the project.

Active Team Members by Role	Number of Participants
▪ Project Manager (1 CFAST 1 SHARE)	2
▪ Clinical Therapeutic Area Experts	2
▪ Medical Writer	1
▪ Statisticians	8
▪ Metadata Developers	6
▪ CDASH Representatives	2
▪ ADaM Representatives	3
▪ SDS Representatives	3
▪ SHARE Representatives	5
▪ Terminology/Clinical Outcome Assessments Representatives	3
Total	**35**

Team members currently identified are listed in a separate spreadsheet to accommodate changes over time. The Prostate Cancer team member list will be maintained in the project document repository.

2.2. Key Sponsors and Participants

Current key participants are shown below. The project also intends to invite participation of relevant medical associations. Other key participants will be added as they are identified.

Stakeholder/Participant	Role
CFAST Therapeutic Area Standards Steering Committee	Program governance and resource allocation.
CDISC	Program and project managment, team members and expert consultants (includes both CDISC employees and volunteers).
C-Path	Program and project managment, team members and expert consultants
TransCelerate BioPharma	Provides project management, clinical expertise, team members and reviewers
US – Food and Drug Administration	Performs review of draft and final documents to ensure data points meet FDA reviewer needs.
US – National Cancer Institute - Enterprise Vocabulary Service	Provides team members and consultants to support controlled terminology development.
CDISC Teams: CDASH, SDS, Terminology, ADaM and SHARE teams	Project liaisons to support the TA standards development resources.
BRIDG Semantic Coordination Committee	If new semantics are needed, the BRIDG SCC will be consulted and will assess if and how new sematics will be incorporated in the model.

2.3. Literature Review and References

(Example: References consulted include relevant NIH, FDA and EMEA guidance, literature and CDEs. A complete list of relevant guidance, articles and publications for this indication can be found on the CDISC team portals.)

3. Relevant Project Documents

Related documents to this Prostate Cancer Project Charter are:

- Prostate Cancer Team Member List (to be updated as required throughout the project)
- Prostate Cancer Concept Listing Spreadsheet
- Prostate Cancer Scoping & Planning Checklist
- Prostate Cancer Project Plan *(Note that a complete CFAST/SHARE joint project plan is still under development to be used as a template for future TAUG developments)*

4. Date of TAPSC Approval:

25th February 2016