Project Charter

Name of Project: **Asthma Therapeutic Area Data Standards**

January 28, 2013

Project Manager: Rhonda Facile (CDISC)

1. **Project Team Members**
   Team members currently identified are listed in a separate roster, which will be maintained in the CDISC Portal, to accommodate changes over time.

2. **Estimated Number of Active Project Team Members**
   Team members fall into five groups with different kinds of participation roles in the project. Two of the groups (core team members and consultants) generally participate in the work of multiple therapeutic area projects. Consultants are called in as needed, so require a lesser time commitment. Two other groups (TA team members and reviewers) are recruited for the particular therapeutic area project. Reviewers participate in review of deliverables at the end of each stage. Finally, members of existing standards teams will serve as liaisons to the project. An individual may fulfill roles in more than one group.

Group	Number of Participants
Core team	7
Consultants	6
TA team	8
TA reviewers	5
Standards team liaisons	3

   Note that both program level and project level support will be needed for the life of the TA Standards Development Program as envisioned by the CFAST committee. See the asthma project team roster for details.

3. **Document Repository Location**
   Project documents will be maintained in an Asthma TA project area in the CDISC portal accessible to all team members on the CDISC website (www.cdisc.org)

4. **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 consultants (includes both CDISC employees and volunteers).
TransCelerate BioPharma	Provides clinical expertise, team members and reviewers recruited through member companies.
FDA	Performs review of draft and final documents to ensure data points meet FDA reviewer needs.
NCI EVS	Provides team members and consultants to support controlled terminology development.
CDISC Teams: BRIDG, CDASH, SDS, Terminology and ADaM	Project liaisons to support the TA standards development resources.

5. **Team/Project Description/Scope**

The Asthma 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 Asthma project is the first project to start under the CFAST initiative.

The project is scoped to achieve its deliverables within a time frame of 10 months as agreed by CFAST. The project scope will include data to support endpoints for clinical studies in support of drugs for asthma in adults. Data specific to pediatric studies, studies solely for healthcare utilization (pharmacoeconomics) and Chronic Obstructive Pulmonary Disease (COPD) are considered out of scope for this first version of standards for Asthma. However, some of the standards developed for Asthma are likely to be useful for other therapeutic areas (including COPD) in the future. The following table summarizes the content planned for this project, and the type of effort that will be needed to manage it. Additional detail is available in a separate scoping document.

Type of Data	Magnitude	Gap Analysis
Pulmonary Function Tests	~10 tests	Opportunity to develop the metadata for physiological assessments of the respiratory system. There are similar physiology domains already developed to facilitate this process.
Biomarkers	10-20 tests	These are mainly lab tests, for which SDTM and CDASH standards already exist. Some tests have controlled terminology defined. New test development will follow established processes.
Concomitant Medications	~5 categories of medications	Generally covered by existing concomitant medication standards. May require recommendations on types of drug categories of interest.

Healthcare Utilization	Data on hospitalizations	These data are needed for the evaluation of seriousness of exacerbations. There is an opportunity to develop metadata for hospitalization information to support analysis of asthma exacerbations in future versions of this standard.
Asthma Symptoms	5-10 standard questionnaires Guidance on other symptom severity assessments.	Development of controlled terminology for questionnaires is a routine process. The SDTMIG and the Pain User Guide provide precedents for handling symptom severity assessments by means other than standard questionnaires.
Exacerbations	Covered by Adverse Events, Concomitant Medications, Clinical Events and Hospitalizations.	Will not attempt to define standards for exacerbation severity. However, additional standards will be developed, where needed, for data generally used to assess severity of exacerbations.

6. References

References consulted included relevant NIH, FDA and EMEA guidance, literature and CDEs. A complete list of references can be found on the CDISC team portals.

7. Project Deliverables

Project deliverables will include:

- Essential core data elements with definitions, data types (simple & ISO 21090), BRIDG and SDTM mappings
- Mind map/concept map of disease area clinical concepts
- User/Implementation Guide
- SDTM-based domains and examples, as appropriate
- Minimum value sets (code lists) with definitions and C-Codes, as appropriate
- Statements of permission to publish controlled terminology for copyrighted questionnaires, where applicable.

The project team will also explore the inclusion of annotated CRFs (with CDASH and SDTM-based annotations) and ADaM analyses and examples during the course of the project.

Project deliverables will reference sources and describe provenance used in their creation (such as the use of pre-existing CDEs).

8. **Sub teams/Roles**
The project team will use the standard TA roles described in the TA Role Definition document. This document can be found on the CDISC team portal.

9. **Project Goals/Deliverables/Milestones with Target Dates 2013**
The project will follow the enhanced therapeutic area standards development process. Following is high-level project plan.

Project Stage	Process Phase	Timeline
	Start of Asthma Project (team formation)	November 27, 2012
Stage 1	Complete Identification of Concepts	Q1 2013
Stage 2	Draft Asthma User Guide with Definitions	Q2 2013
Stage 3	Public Review	Q3 2013
	Publish Asthma User Guide v1.0	Q3-Q4 2013

More detailed dates and milestones will be maintained in a separate Asthma project plan.

10. **Project Resources, Gaps and Risks**
- A major potential risk to this ambitious project plan is project resource availability. For this project to succeed, assigned resource must continue be made available to work on project deliverables. It is critical that personnel assigned are able to prioritize the Asthma project above other responsibilities.
- This project remains dependent, to a large extent, on volunteer engagement beyond the resources assigned by TransCelerate BioPharma Inc. (TCB).

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11. **Related Documents**
    - The Asthma Team Member Roster (to be updated as required throughout the project)
    - The Asthma Scoping & Input Concepts Listing (Excel)
    - The Asthma Scoping & Input Checklist
    - The Asthma Project Plan

12. **Date Approved: January 24, 2013**