# QS/FT Sub-Team
## 2014 Team Charter

### Leadership Team

<table>
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<tr>
<th>Core Team Members:</th>
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<td>Gary Cunningham</td>
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<td>Steve Kopko</td>
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<td>Randall Austin</td>
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<td>Richard Lewis</td>
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<td>Cliff Reinhardt</td>
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<td>Janet Siani</td>
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<td>Nate Freimark</td>
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<td>Sandy Lei</td>
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<td>Kim Minkalis</td>
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<td>Jon Neville</td>
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### Core Team Members:
- Jon Neville, Critical Path Institute
- Nate Freima, Critical Path Institute
- Sandy Lei, Columbia University
- Steve Kopko, Critical Path Institute
- Amy Palmer, Critical Path Institute
- Rohit Dhanjal, Critical Path Institute
- Bess LeRoy, Critical Path Institute
- Bob Stafford, Critical Path Institute
- Tom Guinter, Critical Path Institute
- Gary Cunningham, Critical Path Institute

### Stakeholders/Constituency
- Regulatory Authorities
- Standards Development Organizations
- Pharmaceutical Sponsors
- Medical Devices, Diagnostics
- Contract Research Organizations & Consultants
- Academic Researchers
- Laboratories
- Questionnaire Copyright Owners
- Developers of Public Domain Questionnaires

### Team Characteristics

- CDISC SDS QS/FT Sub-Team consists of a core team of 16 that develops enhancements to the foundational SDTMIG QS/FT standard and manages the implementation of standard questionnaires and functional tests to support therapeutic areas. The number of volunteer QS/FT team members is approximately 20. Additional volunteers are welcomed to assist in the internal review of products prepared by the core team.

### Team Mission

**Primary Objectives**
- Define and support the questionnaire and functional test needs of CDISC standards based on the SDTMIG
- Focus on developing standard questionnaire and functional test supplements for publication
  - Implementations will follow the current SDTM/SDTMIG published QS/FT domain models, including any domain assumptions
  - Implementation issues that identify gaps in the current published model will be addressed with the SDS Team for remediation
  - Implementations will be consistent with the SDTMIG, address copyright permission, use controlled terminology, harmonizing on the consistent inclusion of QS/FT variables and standards/best practices for the specific questionnaire being implemented
- Implementations will follow CDISC Operating Procedure 017
- Process improvements to the questionnaire and functional test implementation process to keep pace with the development of CFAST Therapeutic Area Standards/CDISC subject matter experts (i.e. ADaM, Terminology, and CDASH) will be consulted as needed for any input on implementation issues.

### Scope

- The CDISC QS/FT Sub-Team supports the questionnaire needs of all CDISC standards (SDTM, CDASH, and ADaM) and all disease/therapeutic area standards. Based on the new instruments that need to be implemented, the sub-team publishes completed QS/FT Supplements each quarter. The sub-team manages functional test and questionnaire requests based on CDISC COP 017 – QS/FT Implementation Process. QS/FT Supplements have about a 2-4 week implementation cycle after copyright permission is received and QS/FT terminology is released. All approved QS/FT Supplements are stored on the CDISC HOME portal for public access and accessible through the CDISC website.

- The QS/FT sub-team maintains its membership through careful selection of volunteer experts who can contribute to its various sub-teams with their technical or Therapeutic-based subject matter expertise.

### 2014 Deliverables

Deliverables with Projected Target Dates for Public Review:
- QS and FT Supplement Package Updates (Q1-Q4 2014)
- Include EU input to the QS/FT Team review of supplements (Q2-Q3 2014)
- Update content criteria for QS, FT, and a possible new Disease Classification domain (Q2 2014)
- Modeling Questionnaire and Functional Test Results (Q3 2014)
- Representing Questionnaire and Functional Test Metadata (Q4 2014)

### Collaboration

- NCI EVS, SDS, CDASH, ADaM, HL7 RCRIM, CFAST Therapeutic Area standards and CDISC Operations.

### Operating Model & Meetings

- There is a need to develop new SDTMIG QS/FT Supplements for the many existing instruments used in research. Most new disease standards have a potential set of questionnaires and functional tests that need to be implemented in the QS/FT domain as a QS/FT Supplement.
- The requests for these new questionnaire and functional test standards are made to the QS/FT Sub-Team through the TA standards projects and sponsors.
- The Controlled Terminology QS/FT sub-team meets regularly to address QS/FT terminology requests that come from the QS/FT Sub-Tem.
- Other sub-teams teams are convened as needed based on requests.
- Key weekly meetings: 10am-11am ET 1st Wed. 3pm-4:00pm ET 2nd-4th Wed.