CDER COA Qualification Program (CDER COAQP)

COAQP Information Session
Pathways for FDA Engagement

**IND Pathway**
- **Within** an individual drug development program
- Investigational New Drug (IND) submissions to FDA
- Potential to support regulatory decision-making (within the individual drug development program)

**DDT COA Qualification Pathway**
- **Outside** of an individual drug development program
- Development of novel COAs for use in multiple drug development programs addressing unmet measurement needs
- Potential to result in qualification of COA

**Meetings (e.g., Critical Path Innovation Meetings)**
- **Outside** of an individual drug development program
- Informal, nonbinding meetings
- Potential for *general CDER advice* on specific methodology or technology (e.g., COAs, biomarkers)
Important Notes

• Qualification is **not** required for a COA to be successfully used in clinical trials and drug development to support regulatory decision making.

• Formal regulatory qualification is a multi-year process that requires a high degree of commitment.

• Qualified COAs must be made publicly available.
What is Qualification?

• A conclusion that within the qualified COU, the COA can be relied upon to have a specific interpretation and application in drug development and regulatory review.

• Once qualified, the COA can be included in IND/NDA/BLA submissions without needing FDA to reconsider and reconfirm its suitability as long as:
  – There are no serious study flaws
  – There are no attempts to apply the COA outside the qualified context of use
  – There are no new and conflicting scientific facts not known at the time the qualification was determined
CDER COAQP History

• The CDER COAQP in existence >10 years

• 21st Century Cures Act Passed in Dec 2016
  – Formalized the qualification process
  – Established 3 milestone stages
  – Established target dates
  – Transparency provisions
CDER COAQP Stages

Stage 1:
Letter of Intent

Stage 2:
Qualification Plan

Stage 3:
Full Qualification Package

Accept/Not Accept

Accept/Not Accept

Qualified/ Not Qualified
CDER COAQP Stages

Stage 1: Letter of Intent

Stage 2: Qualification Plan

Stage 3: Full Qualification Package

Qualification Determination

Step 1: Reviewability

Step 2: Scientific Review

Step 3: DDT Committee
CDER COAQP Stages

Stage 1: Letter of Intent
Stage 2: Qualification Plan
Stage 3: Full Qualification Package
Qualification Determination

Important Notes:
• Requestors can (and are encouraged to) obtain feedback from the FDA in between stages
• Requestors cannot skip stages
CDER COAQP Stages

Stage 1: Letter of Intent
Stage 2: Qualification Plan
Stage 3: Full Qualification Package
Qualification Determination

MEETING REQUESTS
OTHER SUBMISSIONS
Letter of Intent

• High-level proposal
  – Concept(s) of interest
  – Target context of use
  – Description of the measure
  – Unmet need need for the instrument
Qualification Plan

• Qualitative Evidence
  – Qualitative study protocol
  – Qualitative results
  – Interview Guides

• Quantitative (Statistical) Analysis Plan
Full Qualification Package

• Qualification Plan Documents
  – Qualitative study protocol
  – Qualitative results
  – Interview guides
  – Quantitative (Statistical) Analyses Plan

• Results from Quantitative Analyses

• Datasets
QRT and DDT Committee

Qualification Review Team

DDT Committee

- Senior CDER officials
- Decisional body
Important Notes on Submission

• Include the **full study report** along with **study protocols**. Manuscripts may not always contain sufficient details.

• LOIs, QPs, and FQPs are meant to be organized, **stand-alone** submission packages.
  – Table of Contents
  – Inventory appendices and attachments
  – Able to navigate

• Ensure the most recent LOI/QP/FQP outline is used.
Review Clocks

<table>
<thead>
<tr>
<th>Qualification Stage</th>
<th>Review Clocks</th>
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<tbody>
<tr>
<td>Letter of Intent (LOI)</td>
<td>3 months (calendar days)</td>
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<tr>
<td>Qualification Plan (QP)</td>
<td>6 months (calendar days)</td>
</tr>
<tr>
<td>Full Qualification Package (FQP)</td>
<td>10 months (calendar days)</td>
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Review clock does not begin until the LOI/QP/FQP is deemed reviewable.
If Reviewable:
START!

Review Clock

Date
Submission
Rec’d

Reviewability
Date

FDA Meetings

Goal Date

Not
Reviewable

Reviewability
Memo

FDA Letter
## Transparency Provisions

<table>
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<tr>
<td><strong>LOI/QP/FQP Submissions</strong></td>
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<tr>
<td><strong>FDA LOI/QP/FQP Determination Letters</strong></td>
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<tr>
<td><strong>Submissions that “significantly updates” DDT COA project</strong></td>
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<tr>
<td><strong>FDA response these submissions</strong></td>
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The LOI/QP/FQP outlines describe what sections will be publicly posted.
Tips When Submitting LOI

1. The first 4 sections of an LOI posted online and should be standalone sections.

2. Some requestors may be further along when submitting their LOI. Please do not submit protocols or study results from qualitative or quantitative research with the LOI.

3. More than 1 LOI may be needed if there is:
   – >1 context of use
   – >1 COA instrument
CDER COAQP RESOURCES
CDER COAQP Email Listserv

**COA Qualification Program (Drug Development Tool) Email Listserv**

- Announcing newly qualified COAs
- Sharing updates to existing COAQP resources (e.g., Letter of Intent [LOI] outline edits, etc.)
- Communicating COAQP process changes (e.g., switching electronic submission portals)
Division of Clinical Outcome Assessment (DCOA)

Mission
Integrating the patient voice into drug development through COA endpoints that are meaningful to patients, valid, reliable and responsive to treatment.

General Information
- DCOA: Who We are and What We Do
- Clinical Outcome Assessments (COA): Frequently Asked Questions
- DCOA Contact Information

CDER COA Qualification Program
- CDER COA Qualification Program Overview
- CDER COA Qualification Program FAQs
- CDER COA Qualification Program Resources
- Qualified COAs
- CDER COA Qualification Program Submissions

COA Compendium

www.fda.gov/coa
General Information

- **DCOA: Who We are and What We Do**
- **Clinical Outcome Assessments (COA): Frequently Asked Questions**
- **DCOA Contact Information**

**CDER COA Qualification Program**

- **CDER COA Qualification Program Overview**
- **CDER COA Qualification Program FAQs**
- **CDER COA Qualification Program Resources**
COAQP Email Updates

Subscribe for COAQP emails. Receive timely communications such as procedural changes, newly qualified COAs and other COAQP related announcements.

### COAQP Stages and Submissions

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<th>Content Element Outlines</th>
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<td>Stage 3</td>
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CDER COAQP Email Address

COADDTQualification@fda.hhs.gov
Thank you!