CDER COA Qualification Program (CDER COAQP)

COAQP Information Session

Pathways for FDA Engagement

IND Pathway	DDT COA Qualification Pathway	Meetings (e.g., Critical Path Innovation Meetings)
Within an individual drug development program	Outside of an individual drug development program	Outside of an individual drug development program
Investigational New Drug (IND) submissions to FDA	Development of novel COAs for use in multiple drug development programs addressing unmet measurement needs	Informal, nonbinding meetings
Potential to support regulatory decision-making (within the individual drug development program)	Potential to result in *qualification* of COA	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?

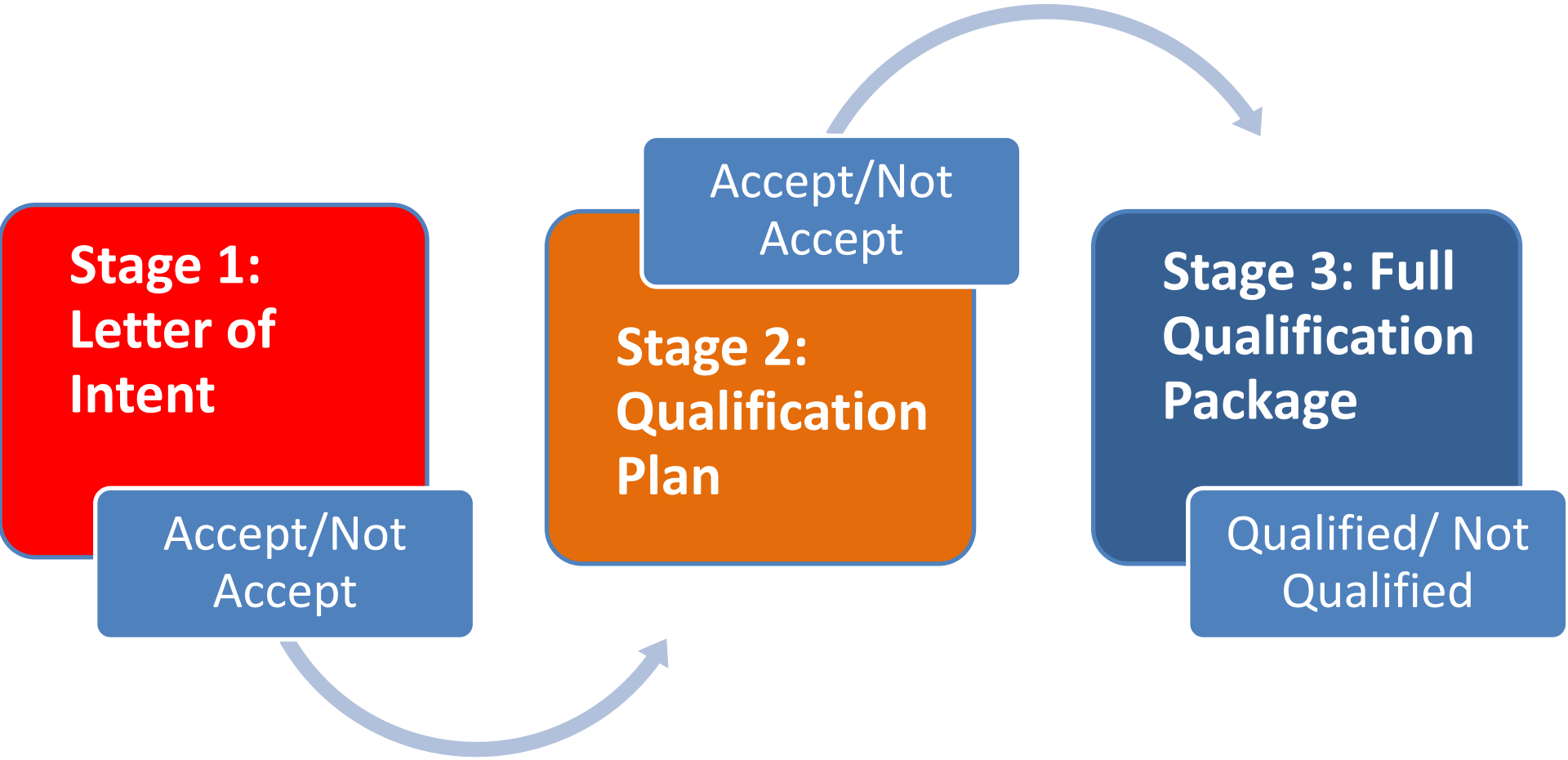
- A conclusion that within the qualified COU, the COA can be relied upon to have a specific interpretation and application in drug development and regulatory review.
- Once qualified, the COA can be included in IND/NDA/BLA submissions without needing FDA to reconsider and reconfirm its suitability as 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

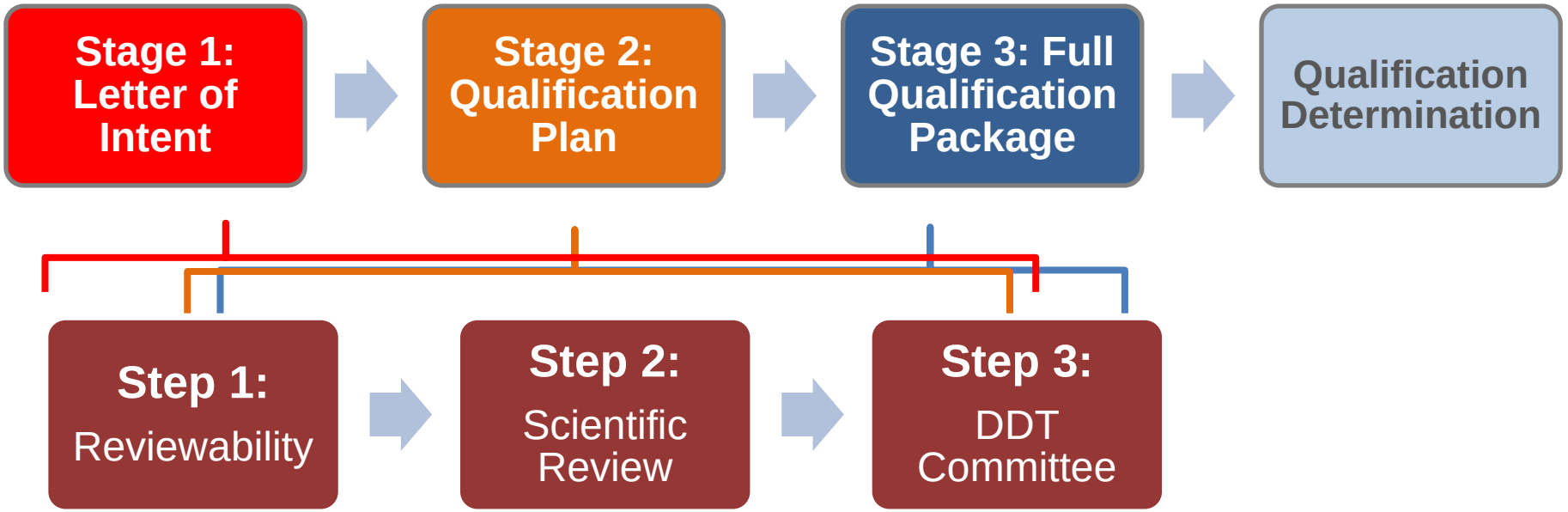
- The CDER COAQP in existence >10 years

- 21st Century Cures Act Passed in Dec 2016
  - Formalized the qualification process
  - Established 3 milestone stages
  - Established target dates
  - Transparency provisions

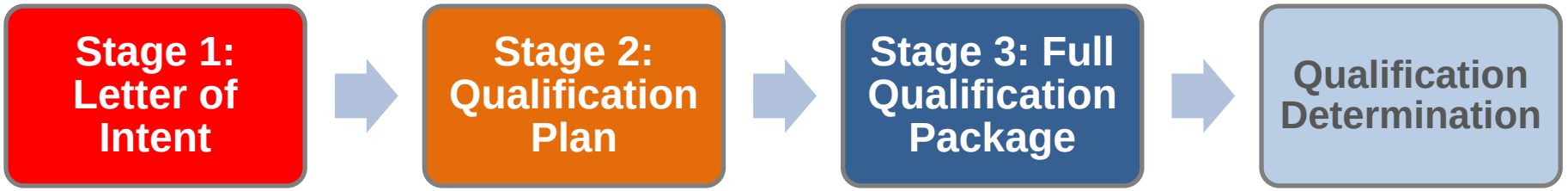
CDER COAQP Stages



CDER COAQP Stages



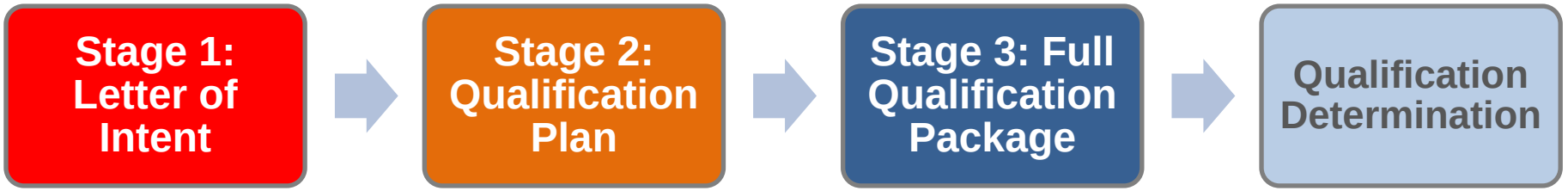
CDER COAQP Stages



Important Notes:

- Requestors can (and are encouraged to) obtain feedback from the FDA in between stages
- Requestors cannot skip stages

CDER COAQP Stages



Letter of Intent

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

Qualification Plan

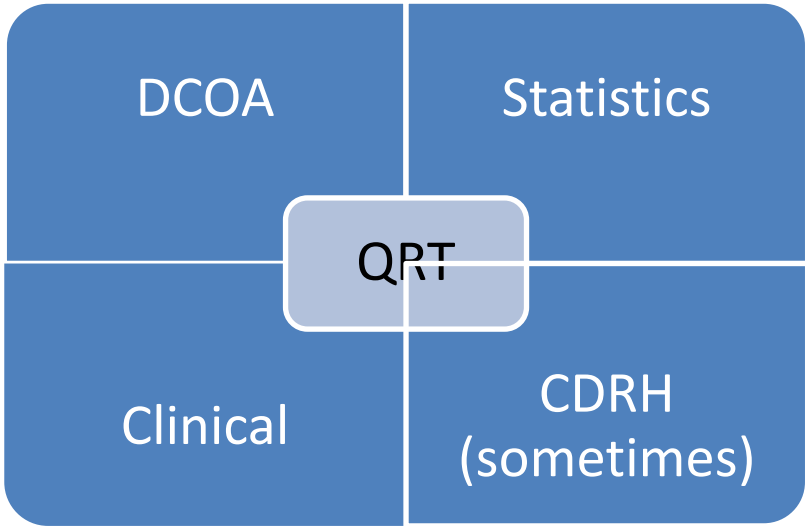
- Qualitative Evidence
  - Qualitative study protocol
  - Qualitative results
  - Interview Guides
- Quantitative (Statistical) Analysis Plan

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.

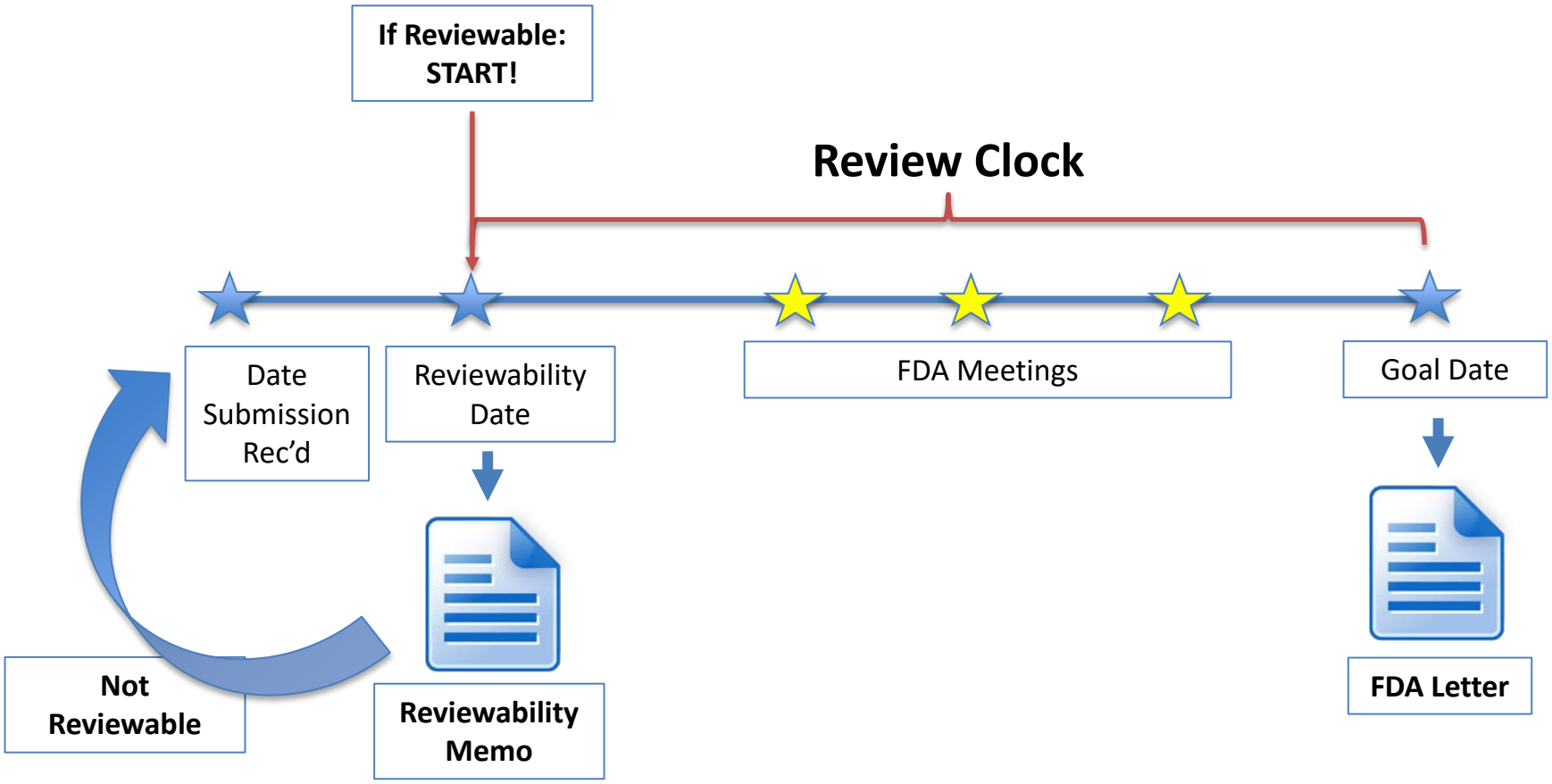
- LOIs, QPs, and FQPs are meant to be organized, **stand-alone** submission packages.
  - Table of Contents
  - Inventory appendices and attachments
  - Able to navigate

- Ensure the most recent LOI/QP/FQP outline is used.

Review Clocks

Qualification Stage	Review Clocks
Letter of Intent (LOI)	3 months (calendar days)
Qualification Plan (QP)	6 months (calendar days)
Full Qualification Package (FQP)	10 months (calendar days)

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

Required to Post:	
LOI/QP/FQP Submissions	FDA LOI/QP/FQP Determination Letters
Submissions that “significantly updates” DDT COA project	FDA response these submissions

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)

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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

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Clinical Outcome Assessments (COA) Qualification Program Resources

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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

Stage	Content Element Outlines
Stage 1	Letter of Intent (LOI)
Stage 2	Qualification Plan (QP)
Stage 3	Full Qualification Package (FQP)

U.S. FOOD & DRUG ADMINISTRATION

CDER COAQP Email Address

COADDTQualification@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

Thank you!