Update on the Clinical Outcome Assessment Qualification Program

Sixth Annual
PRO Consortium Workshop April 29-30, 2015

Ashley F. Slagle, MS, PhD
Study Endpoints Staff
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)

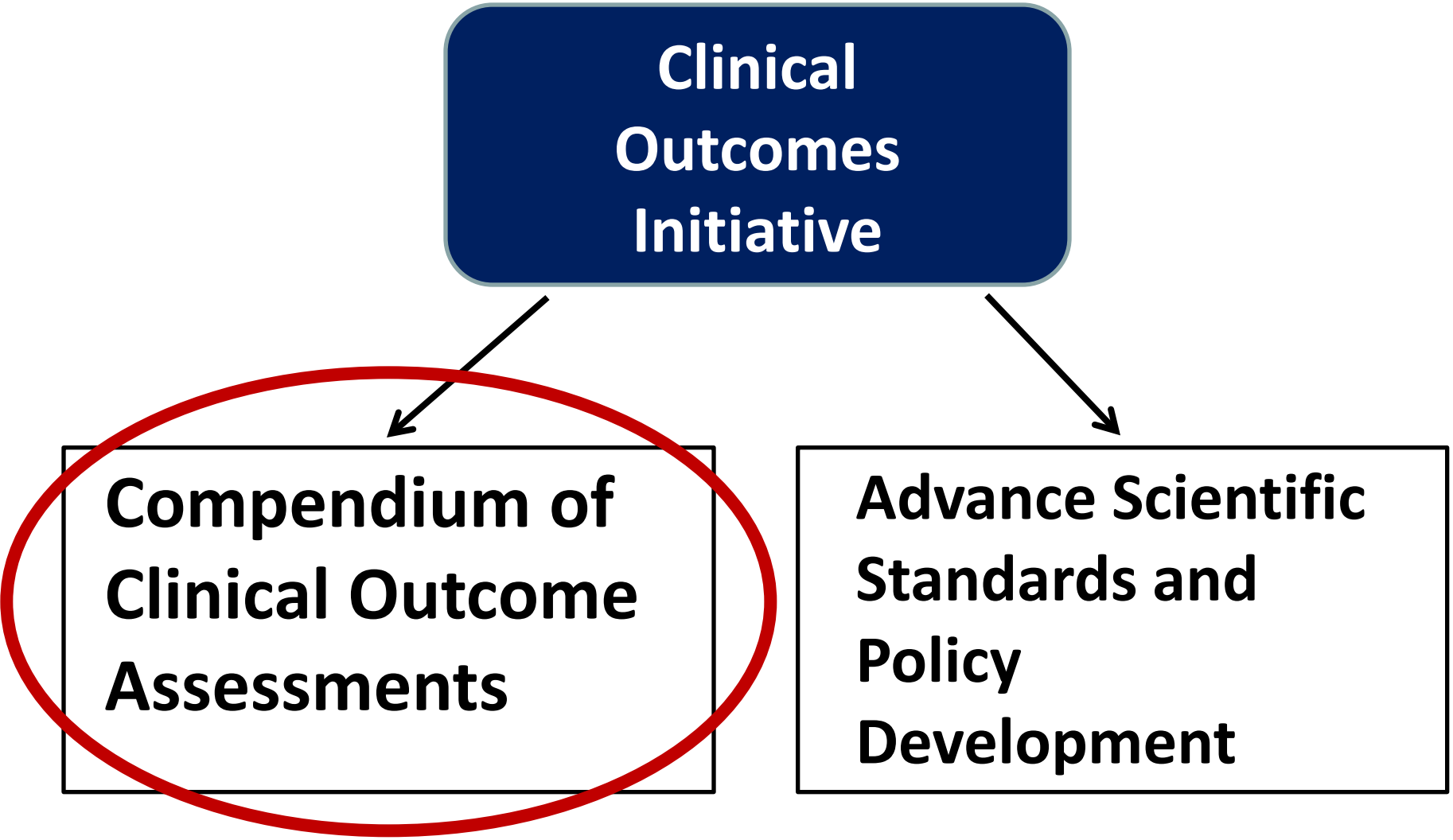
Disclaimer

- The views expressed in this presentation are those of the speaker, and do not necessarily represent an official FDA position

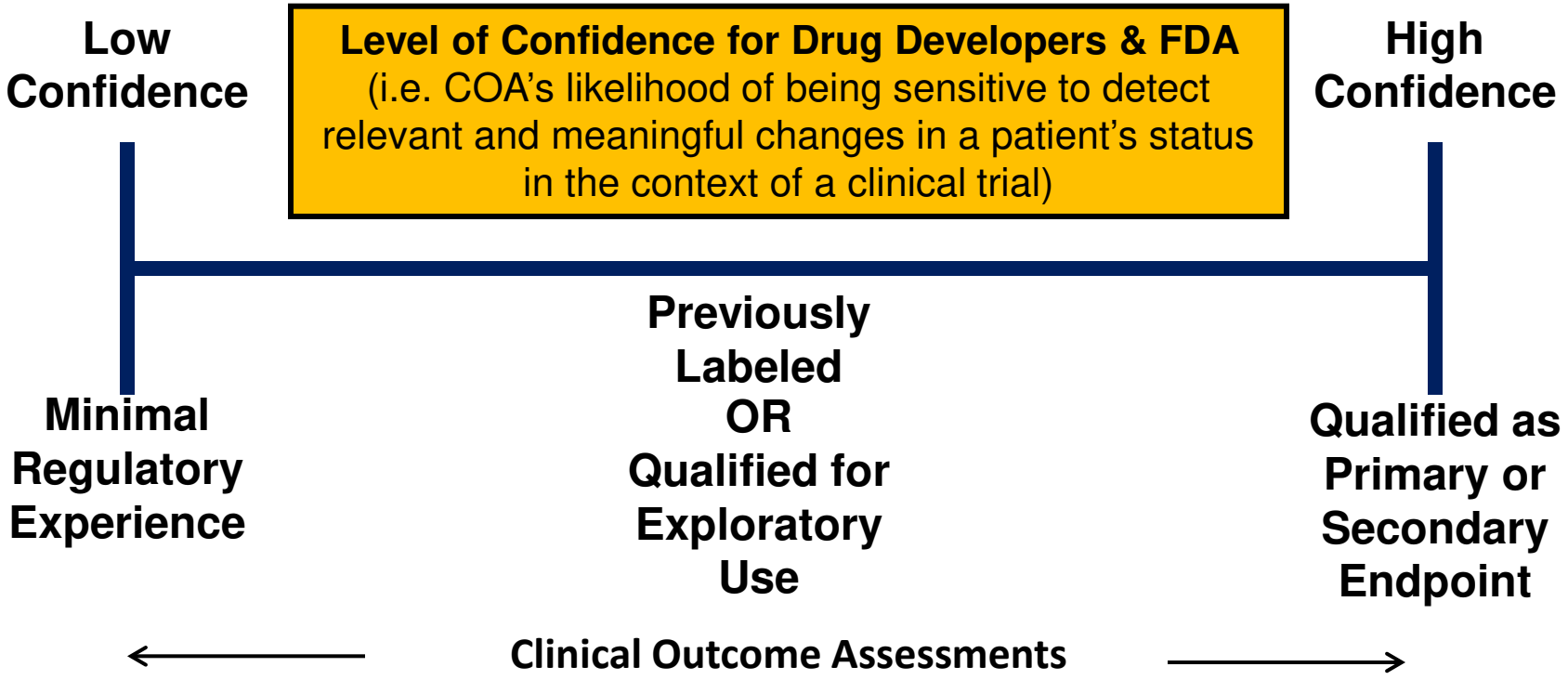
Overview

- Qualification as part of broader COA Initiative
- Update on FDA COA Qualification Submissions and Related Activities
- FDA/EMA Parallel Qualification Reviews

Qualification and the Broader COA Initiative


Clinical Outcomes Initiative
Compendium of Clinical Outcome Assessments
Advance Scientific Standards and Policy Development

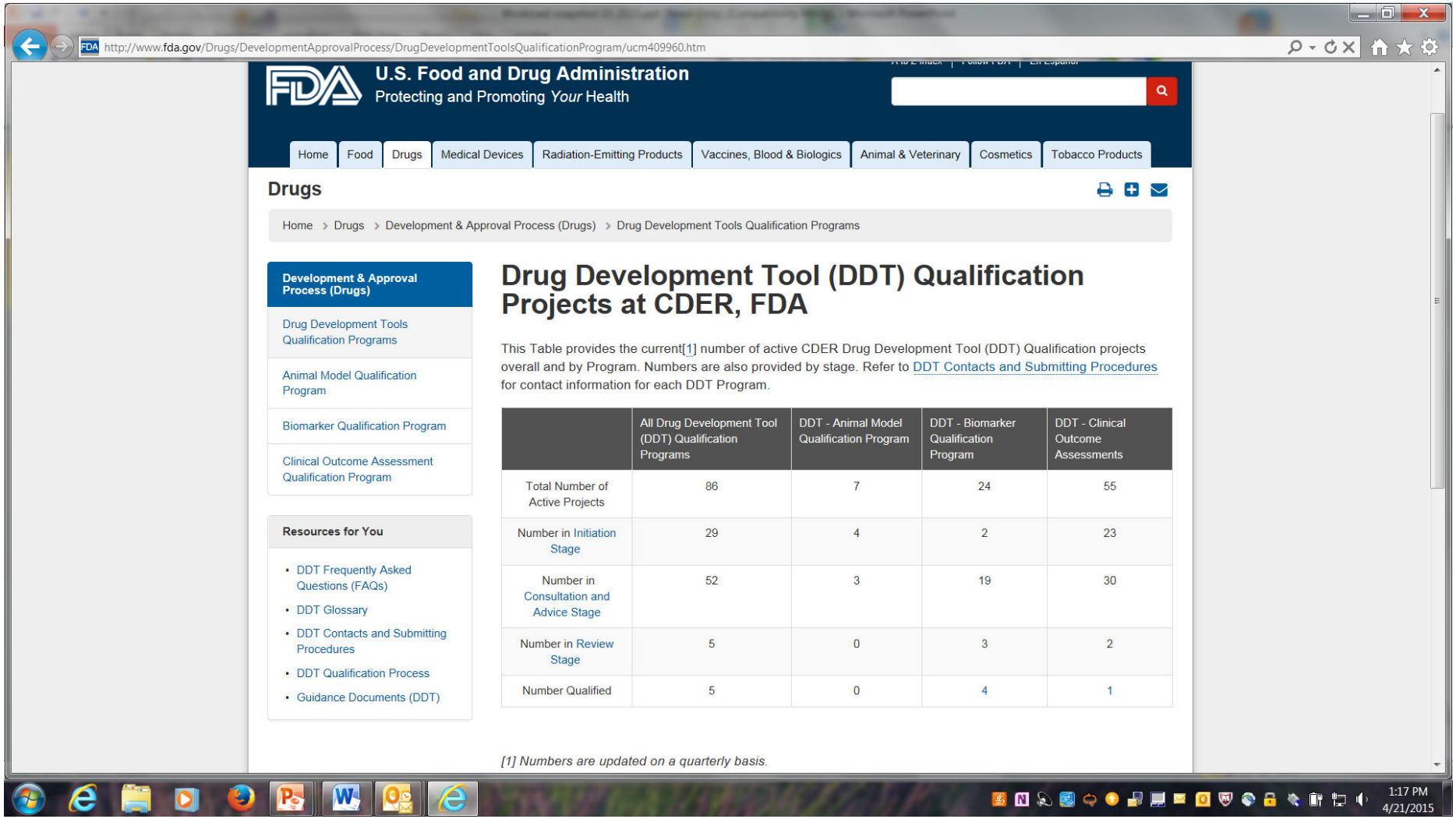
FDA's Review of COAs to Support Labeling Claims



Update on FDA COA Qualification Submissions and Related Activities

COA Qualification Projects

COA DDT Stage	Number in Stage as of Q1 2015
Initiation Stage	23
Consultation and Advice Stage (C&A)	30
Review Stage	2
Total	**55**
Qualified for Use in Exploratory Studies	**1**



http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/ucm409960.htm

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Drugs

Home › Drugs › Development & Approval Process (Drugs) › Drug Development Tools Qualification Programs

Development & Approval Process (Drugs)

- Drug Development Tools Qualification Programs
- Animal Model Qualification Program
- Biomarker Qualification Program
- Clinical Outcome Assessment Qualification Program

Resources for You

- DDT Frequently Asked Questions (FAQs)
- DDT Glossary
- DDT Contacts and Submitting Procedures
- DDT Qualification Process
- Guidance Documents (DDT)

Drug Development Tool (DDT) Qualification Projects at CDER, FDA

This Table provides the current[1] number of active CDER Drug Development Tool (DDT) Qualification projects overall and by Program. Numbers are also provided by stage. Refer to DDT Contacts and Submitting Procedures for contact information for each DDT Program.

	All Drug Development Tool (DDT) Qualification Programs	DDT - Animal Model Qualification Program	DDT - Biomarker Qualification Program	DDT - Clinical Outcome Assessments
Total Number of Active Projects	86	7	24	55
Number in Initiation Stage	29	4	2	23
Number in Consultation and Advice Stage	52	3	19	30
Number in Review Stage	5	0	3	2
Number Qualified	5	0	4	1

[1] Numbers are updated on a quarterly basis.

1:17 PM
4/21/2015

COA Qualification Challenges in 2014

- Limited Staff Resources
  - Study Endpoints staff in 2014 = 5
- Delays in responses to COA qualification submissions
  - Continuing to work through the backlog from 2014
- Unable to accept all proposed projects into qualification program
  - Decisions made by weighing staff resources with anticipated public health benefit and measurement gap proposed to be filled

COA Qualification Successes in 2014

- EXACT-PRO qualification and DDT Qualification final guidance

- Added Qualification Q&As to website
- Interest and growth in COA qualification program continues

- Continued partnerships
  - Among review divisions and Study Endpoints Staff
  - With regulators, consortia, individual investigators, academics, other government partners, and patient groups
  - Among FDA and EMA

COA Qualification 2015 and Beyond

- Improved COA Staff Resources
  - Study Endpoints staff in 2014 = 5
  - Study Endpoints staff in 2015 = 11
- In the process of establishing timely and realistic response timelines
- Continuing to carefully evaluate proposals in order to use resources strategically
  - Goal with qualification is to fill the most needed measurement gaps and maintaining timely responses to submissions

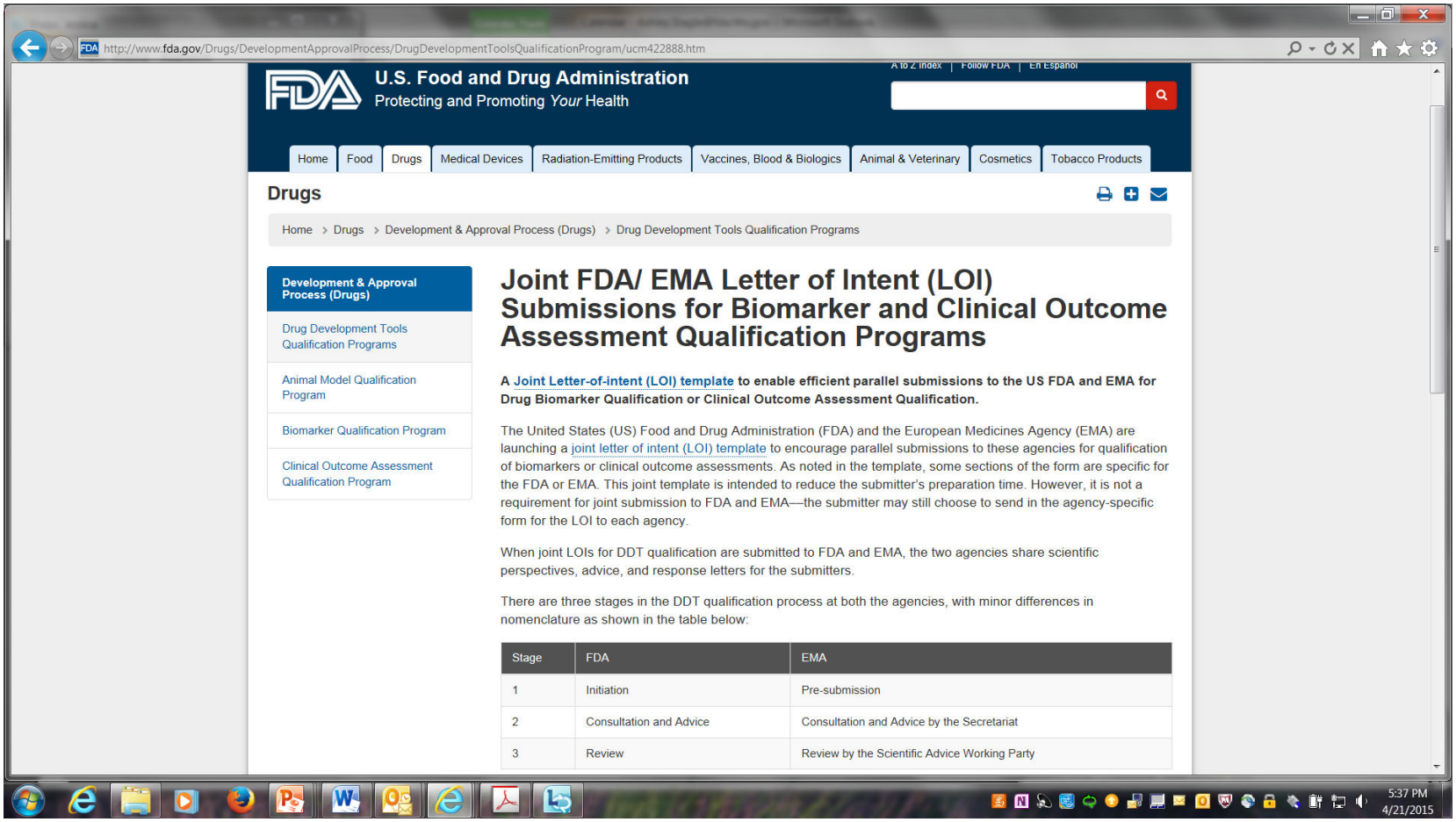
COA Qualification 2015 and Beyond

- Letters to Qualification Submitters, requesting:
  - Status updates
  - Permission to share qualification efforts publically (e.g., compendium)

- Continue to partner with various stakeholders (e.g., consortia, academic investigators, pharmaceutical companies, patient groups) to develop and ultimately qualify needed patient focused outcome measures

Parallel Qualification Activities with EMA

Joint Letter of Intent template for submissions to both FDA and EMA



Parallel Qualification Activities with EMA

- We encourage submitters to consider engaging in qualification with both FDA and EMA
- Currently, 4 qualification efforts are underway with FDA and EMA ("parallel review")
- Goal of parallel review: coordination and harmonization *to the extent possible* in order to minimize conflicting advice and decisions from EMA and FDA
  - Given different regulations, parallel reviews unable to be consensus defining
  - Both agencies make individual qualification recommendations and decisions and issue independent response letters

Parallel Qualification Activities with EMA

- FDA participates as observers in EMA-submitter meetings/teleconferences and EMA participates as observers in FDA-submitter meetings/teleconferences
- Quarterly meetings for FDA and EMA to discuss status of ongoing DDT projects and opportunities for collaboration
- Ad hoc meetings (and email communication) to discuss individual DDT projects, including scientific questions, timelines, and process
- Each Agency shares response letters with the other Agency when sending to submitters

Thank you