Update on CDER's Drug Development Tool Qualification Program

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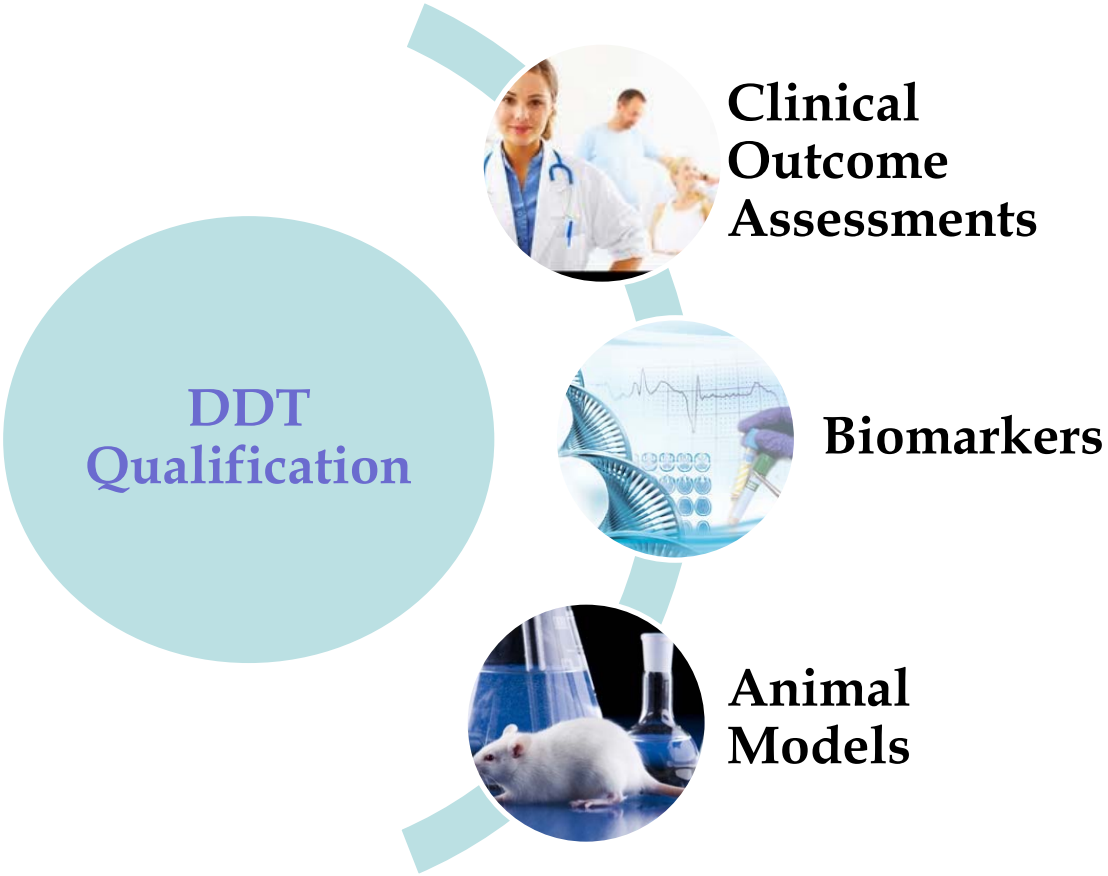
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Develop an approach for FDA to actively advise DDT developers and provide concurrence for DDT use that is not limited to a single, specific drug development program. The value to the public health will be increased when new DDTs become widely known and available for use by all drug developers.

DDT Qualification Activities




WARNING
CHALLENGES
AHEAD

August 2006

Sent: Friday, August 11, 2006 9:50 AM
To: Shames, Daniel A
Cc: Monroe, Scott
Subject: Proposal for a Universal PRO for Women's Menopausal Symptoms introduced to PhRMA
Importance: High

Dear Dan,

Our proposal to the CRTG Group of PhRMA to lead an initiative under their Pre-Competitive Space Strategy for the development of an independently designed universal PRO for Women's Menopausal Symptoms has met with initial positive feedback. As we develop this proposal further, Darrick Fu suggested that this is a topic that PhRMA should discuss with Dr. Murphy, head of Translational Medicine at the FDA as it fits with the Critical Path Initiative.

Perhaps you could consider discussing this opportunity with Dr. Murphy? It would be a terrific step forward in drug development and so many patients would benefit.

Thanks for your consideration.

cheers

Best Regards,

December 2007

From: Darrick Fu
Sent: Wednesday, December 05, 2007 8:48 PM
To: (jean-louis.saillot@spcorp.com); Anupama Kalsekar; bobulaj@wyeth.com; Gail Farfel (gail.farfel@novartis.com); J. Michael Woolley; joseph.jackson@bms.com; julie_chandler@merck.com; mrothman@psmus.jnj.com; priti.m.jhingran@gsk.com
Cc: 'Joseph Camardo'
Subject: Precompetitive PRO Questionnaire

PhRMA PRO consortium team –

Attached please find the final "template" for reporting your companies areas of precompetitive interest to PhRMA. Please coordinate within you companies to prepare a single response per company and forward to me by COB Jan 2, 2008. Aggregated results will be prepared for discussion at our Jan 7th teleconference with FDA.

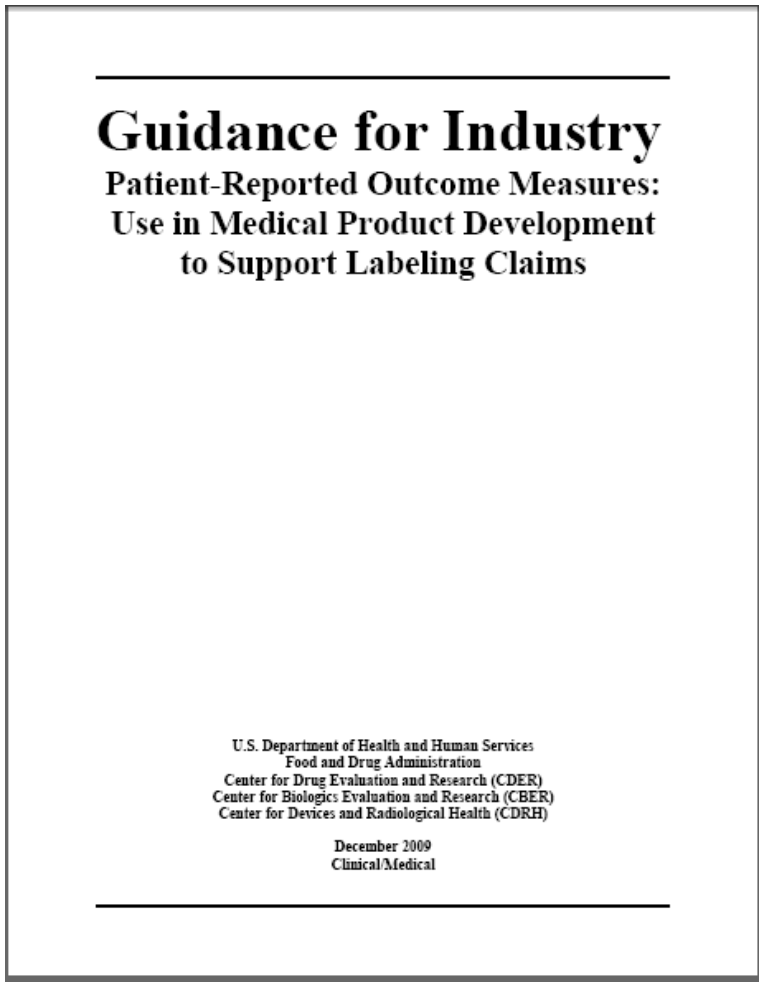
In considering your responses in may be very important to consider the timeframe 3-5 years from now rather than current.

Priti and Gayle, please cascade to PhRMA's HOTG and CRTG respectively. Current CRTG membership list is attached to help facilitate connectivity between company representatives.

Thanks-
Darrick

2009

- Formation of the PRO Consortium with C-Path



Guidance for Industry

Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)

December 2009
Clinical/Medical

October 2010

Guidance for Industry

Qualification Process for Drug Development Tools

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

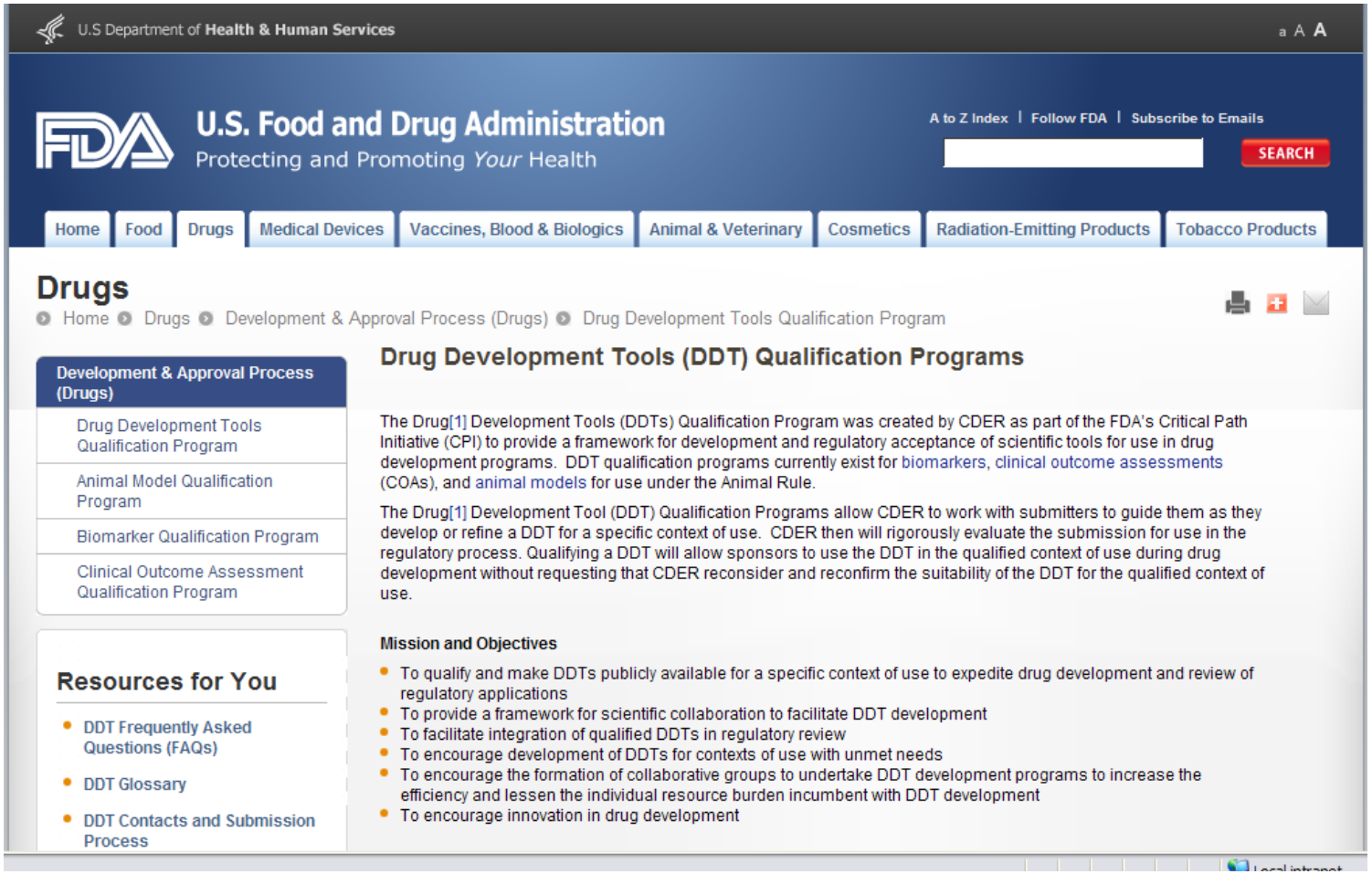
Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Shaniece Gathers, 301-796-2600.

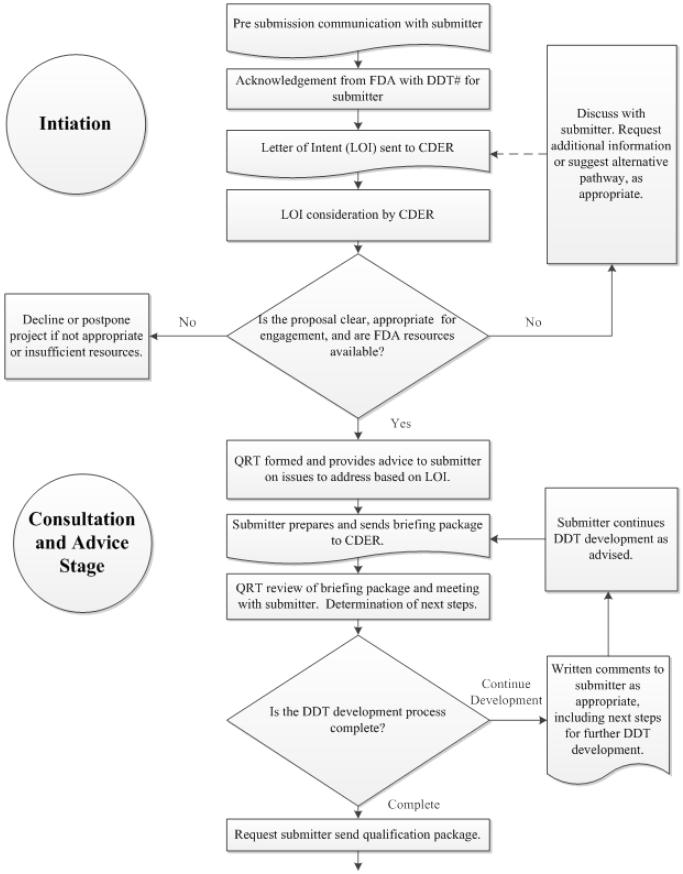

2012
2011

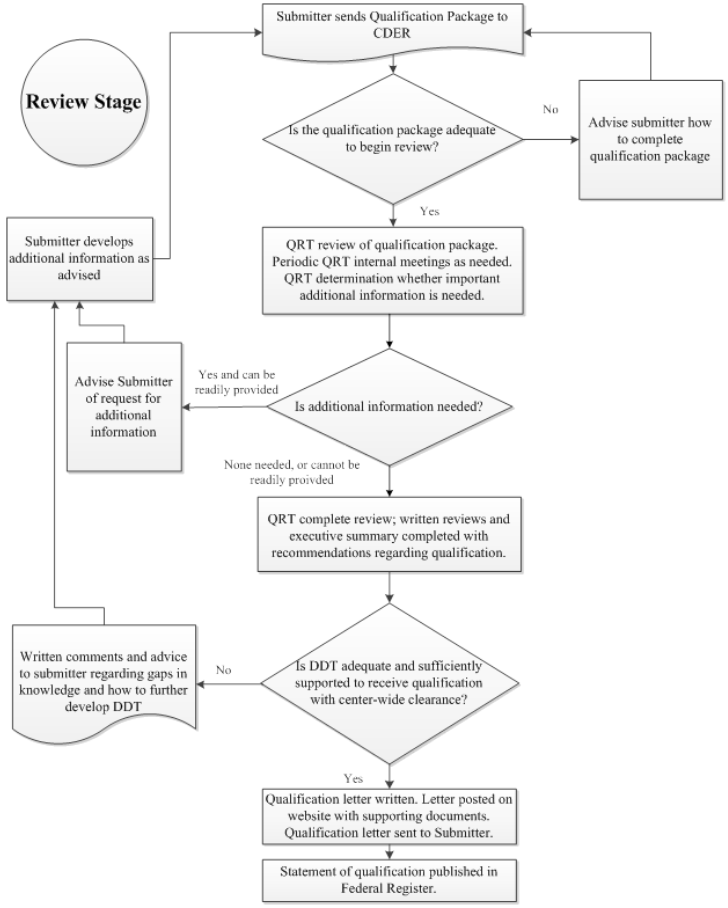
What are we working on currently?

- Finalizing the DDT Qualification Draft Guidance
  - Defining "Context of Use"
  - Letter of Intent and Briefing Package Materials
- Qualification Pathways Established for:
  - Clinical Outcome Assessments
  - Biomarkers
  - Animal Models
- Submissions received in all programs
- Internal and External Websites Launched
- Internal CDER MaPPs (general and program-specific) underway
- Identifying knowledge management and electronic filing tools/capabilities
- Qualification Review Teams forming



www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/default.htm


Intiation
Pre submission communication with submitter
Acknowledgement from FDA with DDT# for submitter
Letter of Intent (LOI) sent to CDER
LOI consideration by CDER
Discuss with submitter. Request additional information or suggest alternative pathway, as appropriate.
Is the proposal clear, appropriate for engagement, and are FDA resources available?
No
Decline or postpone project if not appropriate or insufficient resources.
No
Yes
Consultation and Advice Stage
QRT formed and provides advice to submitter on issues to address based on LOI.
Submitter prepares and sends briefing package to CDER.
Submitter continues DDT development as advised.
QRT review of briefing package and meeting with submitter. Determination of next steps.
Is the DDT development process complete?
Continue Development
Written comments to submitter as appropriate, including next steps for further DDT development.
Complete
Request submitter send qualification package.


Review Stage
Submitter sends Qualification Package to CDER
Is the qualification package adequate to begin review?
No
Advise submitter how to complete qualification package
Yes
QRT review of qualification package. Periodic QRT internal meetings as needed. QRT determination whether important additional information is needed.
Submitter develops additional information as advised
Advise Submitter of request for additional information
Yes and can be readily provided
Is additional information needed?
None needed, or cannot be readily proivded
QRT complete review; written reviews and executive summary completed with recommendations regarding qualification.
Written comments and advice to submitter regarding gaps in knowledge and how to further develop DDT
No
Is DDT adequate and sufficiently supported to receive qualification with center-wide clearance?
Yes
Qualification letter written. Letter posted on website with supporting documents. Qualification letter sent to Submitter.
Statement of qualification published in Federal Register.

Special Thanks!

Shashi Amur
Shaniece Bowens
Laurie Burke
Indira Hills
Dianne Kennedy
Chris Leptak
Susan O'Malley
Suzie McCune
Marianne Noone
Elektra Papadopoulos
Raji Sridhara
Bob Temple
Marc Walton
Sue Jane Wang
Steve Wilson
Issam Zineh

To contact us:

Office of Translational Sciences/CDER/FDA
301-796-2600

shaavhree.buckman@fda.hhs.gov