Update on CDER’s Drug Development Tool Qualification Program

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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

- Clinical Outcome Assessments
- Biomarkers
- Animal Models

DDT Qualification
WARNING

CHALLENGES AHEAD
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, Damon 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,
From: Barrick Fu
Sent: Wednesday, December 05, 2007 8:48 PM
To: (jean-louis.maillot@spoorp.com); Anupama Kalsekar; bobulaj@wyeth.com; Gail Farfel (gail.farfel@novartis.com); J. Michael Woolley; joseph.jackson@bms.com; julie_chandler@merck.com; mrothman@pemus.jnj.com; priti.m.jhingran@ask.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 it may be very important to consider the timeframe 3-5 years from now rather than current.

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

Thanks-
Barrick
2009

- Formation of the PRO Consortium with C-Path
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, 301-796-2500.
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
Drug Development Tools (DDT) Qualification Programs

The Drug Development Tools (DDTs) Qualification Program was created by CDER as part of the FDA’s Critical Path Initiative (CPI) to provide a framework for development and regulatory acceptance of scientific tools for use in drug development programs. DDT qualification programs currently exist for biomarkers, clinical outcome assessments (COAs), and animal models for use under the Animal Rule.

The Drug Development Tool (DDT) Qualification Programs allow CDER to work with submitters to guide them as they develop or refine a DDT for a specific context of use. CDER then will rigorously evaluate the submission for use in the regulatory process. Qualifying a DDT will allow sponsors to use the DDT in the qualified context of use during drug development without requesting that CDER reconsider and reconfirm the suitability of the DDT for the qualified context of use.

Mission and Objectives

- To qualify and make DDTs publicly available for a specific context of use to expedite drug development and review of regulatory applications
- To provide a framework for scientific collaboration to facilitate DDT development
- To facilitate integration of qualified DDTs in regulatory review
- To encourage development of DDTs for contexts of use with unmet needs
- To encourage the formation of collaborative groups to undertake DDT development programs to increase the efficiency and lessen the individual resource burden incumbent with DDT development
- To encourage innovation in drug development
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
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