Best Pharmaceuticals for Children Act (BPCA) Framework to Enable Pediatric Drug Development Resource Submission Form

OVERVIEW

As part of the BPCA mandate, six public assemblies have been convened to develop a generic framework to provide an overall structure to enable pediatric drug development studies. The goal is to develop -- in collaboration with subject matter experts (SMEs) in pediatric care and research -- an annotated, selective, curated collection of resources that will assist drug developers, researchers, and clinicians conducting pediatric drug development research. As part of this process, assembly participants are asked to submit references for best practice and guidance documents for inclusion in the final framework. This online form has been created to streamline this process.

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OMB# 0925-0766 Exp Date: 4/2023

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All submissions must be available in the public domain. All submissions will be compiled and shared with assembly participants for eventual inclusion in the final framework.

Multiple submissions are welcome but you must submit them individually. You may complete this form as many times as you'd like.

*** Which category best applies to your framework submission?**

- ○ General/Overview
- ○ Advancing Clinical Trials
- ○ Biomarkers
- ○ Systems Pharmacology
- ○ Pediatric-Friendly Formulations
- ○ Pharmacoepidemiology
- ○ PK Modeling to Inform Dosing

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Skip Logic Note: This question is only shown if General/Overview is selected for the first question.

*** Which sub-category does your GENERAL DRUG DEVELOPMENT submission fall under?**

- ○ General Drug Development Overview (principles that apply across all populations)
- ○ Pediatric Drug Development Overview (including extrapolation, iPSPs)

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Skip Logic Note: This question is only shown if Advancing Clinical Trials is selected for the first question.

*** Which sub-category does your CLINICAL TRIALS submission fall under?**

- ◯ Clinical Trial Design (Vanilla designs, adaptive designs, platform trials, small and difficult to reach populations)
- ◯ Clinical Trial Conduct (GCP, implementation of GCP, working with networks, decentralized / remote trials)

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Skip Logic Note: This question is only shown if Systems Pharmacology is selected for the first question.

*** Which sub-category does your SYSTEMS PHARMACOLOGY submission fall under?**

- ◯ Pre-clinical/drug discovery
- ◯ Dosing

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Skip Logic Note: This question is only shown if Pharmacoepidemiology is selected for the first question.

*** What sub-category does your PHARMACOEPIDEMIOLOGY submission fall under?**

- ◯ Pharmacoepidemiology studies including post-authorization
- ◯ Real-world data

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*** The final framework will include resources in the areas below. Which option best applies to your submission?**

- ◯ Read this First (single document 10 - 20 pages that give an overview)
- ◯ This is a Helpful Explanation
- ◯ U.S. Guidance
- ◯ Non-U.S. Guidance

Please list the title and reference of your submission below, along with your name, email address, and any comments you may have. REMINDER: All submissions must be available in the public domain.

*** Title/Description**

*** Weblink/Reference**

Name

Email Address

Comments

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Thank you for your submission! If you would like to submit another reference, please click here.

Questions? Contact bpca@infinityconferences.com.