U.S. FOOD & DRUG ADMINISTRATION

PROJECT FACILITATE

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PROJECT FACILITATE

FDA

Overview

- What is Expanded Access (EA)?
- Current Process for Oncology EA Requests
- Project Facilitate
  - Process
  - Benefits

What is Expanded Access?

Current Process for Oncology EA Requests

Current Process

- EA requests may be received by:
  - FDA/CDER's Division of Drug Information (DDI) or
  - by the review Division
- Requests arrive via phone, email, fax, or mail.

Current Process

- If received by DDI, they collect:
  - Physician/requestor name
  - Patient initials
  - Drug/Biologic
  - Drug/Biologic manufacturer
  - Can IRB approval occur prior to treatment?
- DDI forwards to review Division

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Current Process

- Review Division contacts requestor to request:
  - ✓ Signed/completed Form FDA 3926
  - ✓ CV or physician qualifications
  - ✓ Letter of Authorization (LOA)
- Review Division reviews complete request upon receipt
- Review Division informs requestor if they may proceed with treatment

Planned Process for Project Facilitate

Project Facilitate - Process

- Single point of contact for all oncology EA requests
- Patient calls will continue to be supported by DDI staff
- Project Facilitate staff will navigate requestor thru SPI request process, provide:
  - IRB resource options
  - Pharma/biotech contact
  - Advice on other necessary information (e.g. CV, protocol, patient history) to complete their request
  - Assistance completing form FDA 3926, if needed

Project Facilitate – Process

- Requestor contacts drug manufacturer to secure Letter of Authorization (LOA) and cc's Project Facilitate
- If provided, Project Facilitate forwards complete request to appropriate Division
- If not provided, Project Facilitate documents reason, if available (e.g. lack of supply)

Project Facilitate - Benefits

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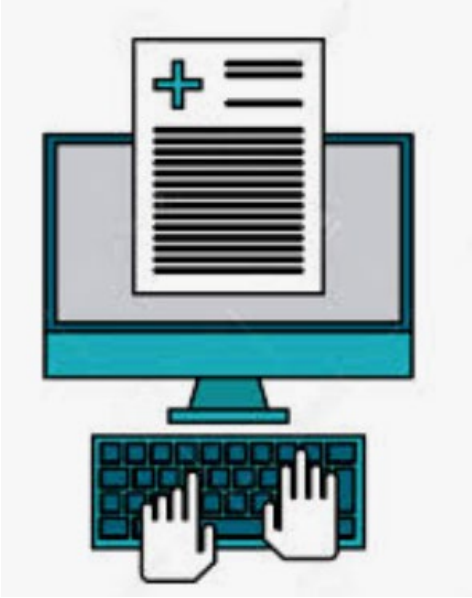
Project Facilitate - Benefits

- Streamline submission: one point of contact for all oncology EA requests (CDER & CBER products)
- Dedicated staff with central, formalized training available during business hours to support requestors via phone or email
  - First phase: staffed by a Lead Regulatory Project Manager, and Regulatory Project Managers from Review Divisions, assigned on rotation
  - Permanent staff may be implemented after assessment of initial phase

Project Facilitate - Benefits

- Step-by-step support in completing request
- Collection of metrics on if access to drug provided by drug manufacturer, and if not, why?
- Follow up / reminders



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