PROJECT
FACILITATE

Oncology Center of Excellence (OCE)

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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
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
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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