Central Resource Management to Facilitate Expanded Access Use of Investigational Products

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BACKGROUND

Expanded access treatment, also called compassionate use or single-patient investigational new drug (IND), is a potential treatment pathway for patients with serious or life-threatening disease who have exhausted all available treatments and are not eligible for a clinical trial. There is a clear need to address and prioritize requests efficiently. Challenges arise due to confusion between clinical care and research support teams regarding the management of these expanded access protocols that aren't technically research protocols.

GOAL

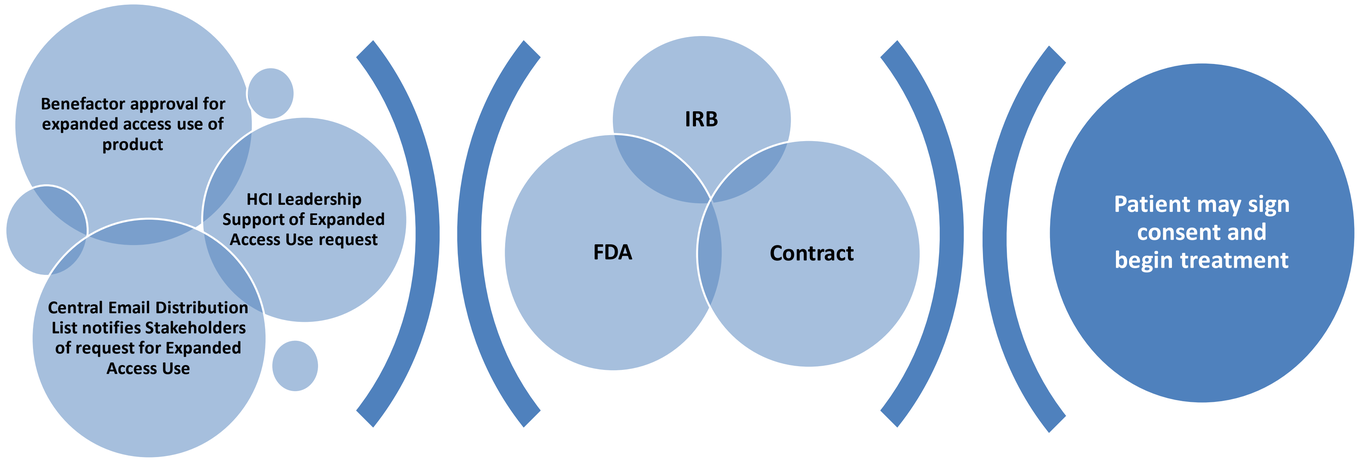
Create a centralized process to ensure all relevant stakeholders are involved from first knowledge of an expanded access use request, allocate and **prioritize resources appropriately** (i.e, Regulatory, Contracts, Pharmacy, etc.), and **maintain safety and regulatory** oversight from start to finish.

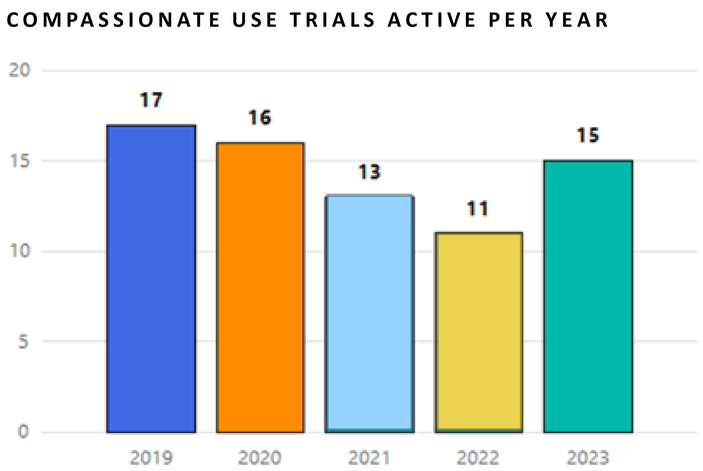
SOLUTIONS AND METHODS

- Develop a central email notification list for stakeholders involved in the initiation process.
- Create a policy defining review and approval of resource allocation.
- Obtain approval by senior research leaders before initiation.
- Outline responsibilities and specific resource needs based on the type of request (single-patient versus multi-patient).
- Train research staff in expanded access protocols, the review process, and requirements for managing these protocols.
- Register and maintain patient records in OnCore.
- Create an eCRF for tracking safety events in our EDC, verified through routine monitoring.

OUTCOMES

- Improved communication among stakeholders
- Ongoing training and regulatory compliance
- Reduced patient safety risks
- Understanding of less-urgent requests due to prioritizations
- Feasibility review encouraged where appropriate; may negotiate with the provider of the investigational product to cover the use of additional resources outside of a clinical trial





FUTURE PLANS

- Enhance coordinated efforts to expand accessibility.
- Continue to be adaptable, as each request for expanded access treatment is different.
- Raise awareness about the central notification pathway for requests.
- Educate providers and staff on the available resources and their roles to improve early notification and facilitate timely activation.
- Collaborate with the hospital to fund a partial FTE in Regulation and the Clinical Trials Office.

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