





HEU – EFS Partner Information

January 2024

Agenda



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103 Key Expectations for HEU-EFS Project

Meditrial's Perspective on HEU-EFS







Clinical Execution

Meditrial runs EFS clinical trials with unparalleled medical expertise and clinical insight. We provide patient engagement, simpler & faster results.



Digital Solutions

Meditrial's tech-enabled solutions help achieve key milestones with the highest speed and lowest possible burden, now vital for our industry and the people we serve.



Regulatory Expertise

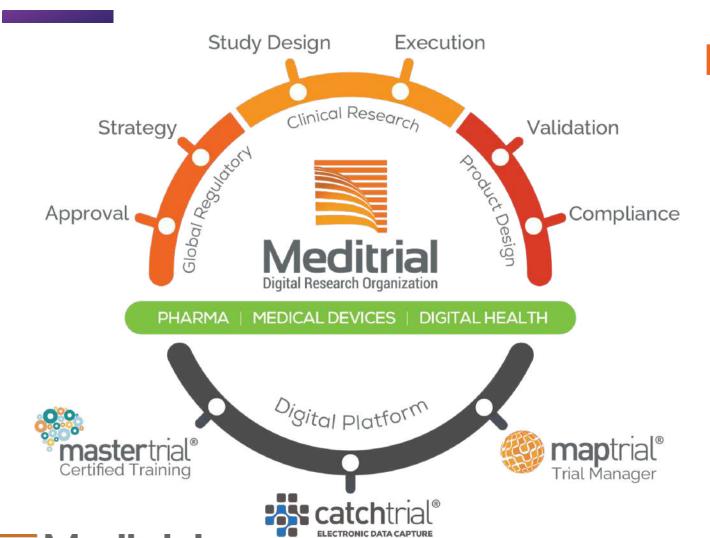
Meditrial clients receive dedicated support throughout the global regulatory, clinical research and product design lifecycle.

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Digital Research Organization





MEDITRIAL PROVIDES A ONE-STOP SHOP DESTINATION FOR EFS TRIALS





Device Technical Documents Expertise

Study Protocol & Trial Management Plan



Investigators /
Sites /
Geographies



Data Management & Real Time Analysis – Best Practices

MEDITRIAL HOLISTIC APPROACH TO CLINICAL TRIALS







STRATEGY

- Plan for Success
- Goals & Design
- Resources

- Budget
- Investigators
- Clinical Sites



DEVELOP CLINICAL DOSSIER

Conformity to:

- Scientific Guidelines
- Center Procedures
- Patient Engagement



MEDITRIAL SUPPORTS EFS STUDIES FROM

START TO FINISH



OBTAIN APPROVAL

- Complete Regulatory Authority IRB Submissions
- Close Contact with Centers
- Budget and Contract Negotiations



MANAGE STUDY

- Fast Initiation
- Rapid Recruitment
- Data Capture
- Results Review



Contact Information





Are you planning an EFS? Contact us today

Website:

www.meditrial.net

Social Media Channels:

- in www.linkedin.com/company/meditrial-today
- x twitter.com/MeditrialToday;
- www.instagram.com/meditrial/;
- www.facebook.com/MeditrialToday/



Key Expectations for HEU-EFS Project (1/2)





Regulatory Excellence

Meditrial is dedicated to providing top-notch regulatory services for the HEU-EFS project, utilizing extensive expertise to ensure compliance, streamline approval processes, and map out the Early Feasibility Study landscape effectively.



Clinical Evidence Generation

We prioritize generating strong clinical evidence and aim to play a key role in designing and conducting the necessary trials for the HEU-EFS project, ensuring meticulous planning and execution to produce high-quality data meeting regulatory standards and offering compelling evidence.



Accelerated Approval & Adoption

Meditrial aims to expedite technology approval and adoption for the HEU-EFS project by leveraging regulatory expertise and efficient clinical trial management, facilitating a smooth transition from early feasibility to pivotal studies, and ultimately delivering technology to patients and healthcare providers quickly.



Global Collaboration and Compliance

Meditrial aims to promote global collaboration in the HEU-EFS project by aligning with diverse regulatory requirements across regions, leveraging our international presence and experience to navigate differences and ensure compliance and harmonization throughout the project's execution.



Key Expectations for HEU-EFS Project (2/2)





Knowledge Transfer and Training

Meditrial is committed to facilitating knowledge transfer and training initiatives within the HEU-EFS project team. We expect to share our insights and best practices, empowering the team with the skills and knowledge required to navigate the intricacies of clinical research and regulatory affairs successfully.



Risk Mitigation

Proactive risk mitigation is a fundamental aspect of Meditrial's approach. We anticipate identifying and addressing potential challenges in real-time, employing effective risk mitigation strategies to ensure the smooth progression of the HEU-EFS project. Our goal is to minimize disruptions, delays, and optimize project outcomes.



Long-Term Collaboration

Meditrial views the HEU-EFS project as the beginning of a long-term collaboration. We aspire to build a strong partnership with the project team, fostering ongoing collaboration beyond the initial stages. This approach ensures sustained success and continued support as the HEU technology progresses through subsequent development phases. We are excited about the opportunities the HEU-EFS project presents, and we look forward to contributing to its success. Meditrial is committed to leveraging its wealth of experience to drive impactful outcomes and advance the field of medical device innovation.



Meditrial's Perspective on HEU-EFS



Early Feasibility Trial are the core of breakthrough innovations that promise to address unmet needs and enhance clinical care. Through Meditrial's work, the patient and innovator are empowered with data and insights from the earliest stage of product clinical evaluation.

Our expert approach focuses on simplifying complexity by contributing to regulatory changes that facilitate EFS trials. We have the ability to transcend the current landscape with "smart" technology enabled data collection tools and insights.







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