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FACILITATE

FrAmework for ClInicaL trIal participants daTA reutilization for a fully Transparent and Ethical ecosystem

WP7 - Business exploitation and Sustainability

D7.1 REPORT ON STAKEHOLDERS' NEEDS AND POTENTIAL BARRIERS

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Definitions

- **Participants** of the FACILITATE Consortium are referred to herein according to the following codes:
  1. **UNIMORE.** Università degli Studi di Modena e Reggio Emilia
  2. **VUB.** Vrije Universiteit Brussel
  3. **TUNI.** Tampereen Korkeakoulousaatio SR
  4. **EUPATI.** Stichting EUPATI Foundation TERMINATED
  5. **ACN**. Associazione Cittadinanzattiva Onlus
  6. **PN.** PRIVANOVA SAS
  7. **ODY**. Odysseus Data services SRO
  8. **ZEN.** Privredno drustvo Zentrix Lab Drustvo sa ogranicenom odgovornoscu Pancevo
  9. **INPECO.** Inpeco SA
  10. **BPE.** ADERA
  11. **AOU.** Azienda Ospedaliero Universitaria di Modena Policlinico
  12. **MUG.** Medizinische Universitat Graz
  13. **UJ.** Universytet Jagiellonski
  14. **IMR.** Institute for Medical Research, University of Belgrade
  15. **SCC.** Spitalul Clinic Colentina Bucuresti
  16. **PNZW.** St Antonius Hospital Gronau Gmbh
  17. **EURAC.** Accademia Europea di Bolzano
  18. **EURORDIS.** EURORDIS – Rare Diseases Europe
  19. **SARD.** SANOFI Aventis Recherche et Développment
  20. **MED.** Mdsol Europe LTD
  21. **ABV.** Abbvie Inc
  22. **AZ.** AstraZeneca AB
  23. **BAY.** Bayer Aktiengesellschaft
  24. **PFZ.** Pfizer limited
  25. **TAK.** Takeda Pharmaceuticals International AG
  26. **ALM**. Almirall SA

27. **SERV**. Institut de Recherches Servier
28. **EUPATI IT.** Accademia del Paziente Esperto EUPATI
29. **BMS.** Bristol Myers Squibb
30. **Roche.** F. Hoffmann–La Roche SA

Linked third parties.
4.1 EUPATI IT. Accademia del Paziente Esperto EUPATI TERMINATED
9.1 INPECO TPM. Inpeco TPM SRL

Abbreviations

D – deliverable
CT – Clinical Trial
EFPIA - European Federation of Pharmaceutical Industries and Associations
HER - Electronic Health Records
EMA - European Medicines Agency
EU - European Union
FDA - U.S. Food and Drug Administration
FHIR - Fast Healthcare Interoperability Resources
GDPR - General Data Protection Regulation
ICF – Informed Consent Form
PMDA, Japan - Pharmaceuticals and Medical Devices Agency
RoD - Return of Data (RoD)
RWE - real-world evidence
SCom - Steering Committee
SDTM - Study Data Tabulation Model
T – Task
WP - Work Package

1. Introduction

This section provides a brief overview of the project's objectives, methodology, and the importance of understanding stakeholders' needs and interests in the pharma and healthcare system, research communities, regulatory authorities, and patients and patient organizations.

1.1 Scope

The primary objective of this report is to understand the needs and interests of stakeholders involved in the healthcare ecosystem, including pharmaceutical companies, clinicians, patients, regulatory bodies, and the research community. By conducting a comprehensive stakeholder analysis, the report aims to identify potential barriers and opportunities for the adoption of the processes and tools developed through the FACILITATE project. Ultimately, this understanding will inform the project's strategy for fostering collaboration, addressing key challenges, and promoting the adoption of innovative data sharing practices.

1.2 Project Overview

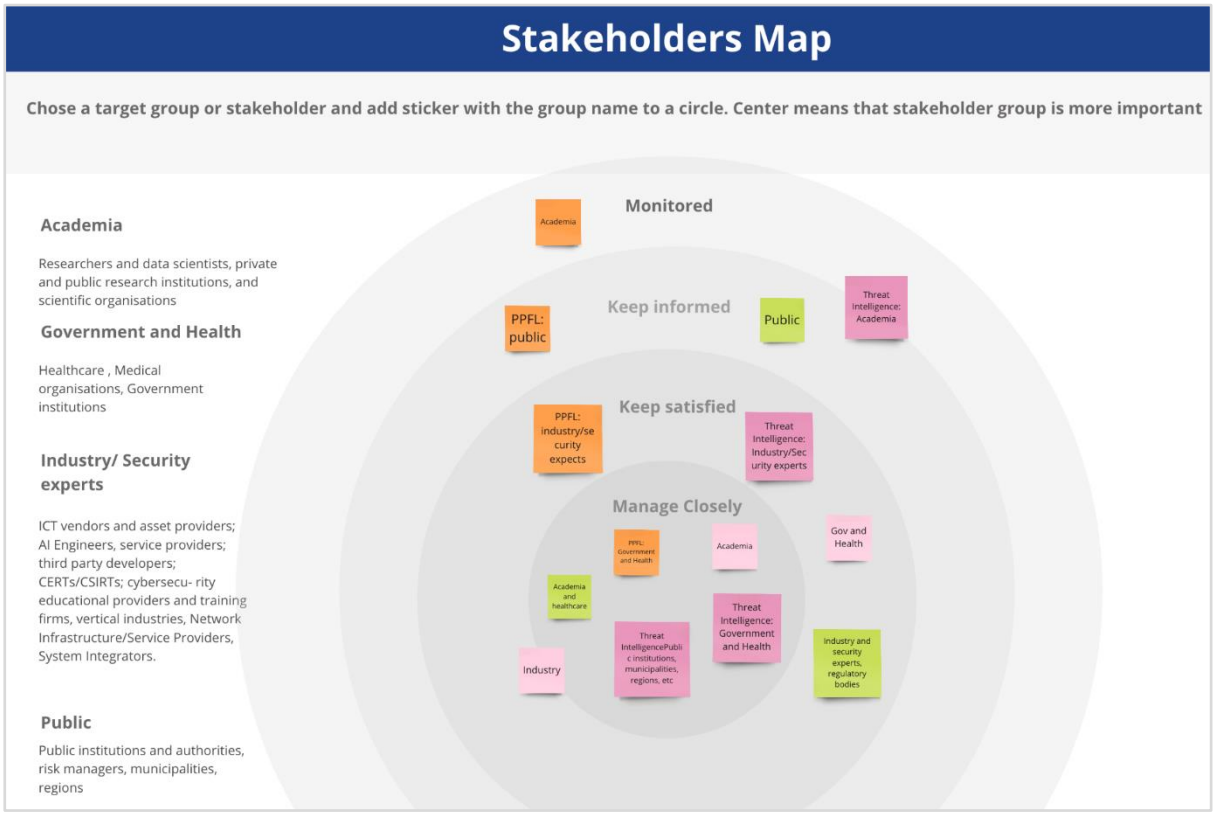
The FACILITATE project is built on the premise of fostering a trusted, ethical, and regulatory-compliant ecosystem for clinical trial data sharing. It seeks to overcome existing challenges where clinical data are often siloed in separate repositories, limiting their potential for broader use beyond their original purpose. By providing clear rules within a trusted framework, FACILITATE enables the return of clinical trial data to study participants while ensuring compliance with data protection regulations, such as GDPR.

1.3 Document organization

The report is structured into several sections, each focusing on different aspects of stakeholder analysis and needs assessment. Section 2 focuses on the "Identification of Stakeholders," outlining the key players involved in the research ecosystem. Section 3 delves into the "Needs Assessment" of these stakeholders, highlighting their specific requirements and challenges. Finally, Section 4 addresses "Dependencies and Potential Barriers," emphasizing the interdependencies among stakeholders and potential obstacles that may hinder effective collaboration and research progress.

2. Identification of stakeholders

The FACILITATE project aims to revolutionize clinical trial data sharing through a patient-centered, data-driven technological platform. Understanding the stakeholders involved is crucial for ensuring the success and adoption of this innovative approach. This section conducts a comprehensive analysis of the stakeholders involved in the pharma and healthcare system, research communities, regulatory authorities, and patients and patient organizations. By analyzing the needs and interests of these diverse stakeholders, the FACILITATE project can tailor its approach to address key concerns, foster collaboration, and promote the adoption of innovative data sharing practices and platform tools in clinical research.



Stakeholder segmentation or mapping is a vital process to categorize stakeholders based on their level of influence, impact, and role as users, adopters, or indirect beneficiaries of the tools developed. This segmentation allows for a clear understanding of each group's criticality in the context of tool adoption and utilization. By identifying high-impact stakeholders versus those with indirect influence, organizations can tailor their engagement strategies accordingly. Categorizing stakeholders by criticality ensures tailored engagement during the exploitation phase. This approach guarantees that each group receives the necessary attention and resources. The goal is to create a seamless, impactful experience for FACILITATE tool users, driving positive change in clinical research and patient care.

2.1 Sponsors of research

In the landscape of clinical research, sponsors play a pivotal role in driving innovation, funding studies, and ultimately advancing medical knowledge and patient care. Within the scope of the FACILITATE project, sponsors of research include pharmaceutical companies and research organizations, each contributing unique perspectives, resources, and expertise to the endeavor

Pharmaceutical companies serve as prominent sponsors of clinical trials, leveraging their financial resources, scientific expertise, and extensive networks to initiate and oversee research initiatives. These companies are driven by a dual mandate: to develop innovative therapies that address unmet medical needs and to navigate regulatory pathways for product approval and commercialization. In the context of the FACILITATE project, pharmaceutical sponsors may contribute data from past and ongoing clinical trials, collaborate on the development of data-sharing protocols, and provide insights into industry best practices and regulatory considerations. Engaging pharmaceutical sponsors ensures that the FACILITATE platform is informed by real-world data and aligns with industry standards and expectations.

Example: Pfizer, Novartis, Roche, Merck

Research organizations encompass a broad spectrum of entities, including academic institutions, research hospitals, non-profit organizations, and government agencies, all dedicated to advancing scientific knowledge and improving patient outcomes. These entities serve as sponsors or collaborators on clinical trials, driving discovery across diverse therapeutic areas and population groups. Research organizations bring a wealth of expertise in study design, data collection, and analysis, as well as access to patient populations and clinical infrastructure. Within the FACILITATE project, research organizations may contribute to the design and implementation of the data-sharing platform, provide clinical insights and domain-specific knowledge, and facilitate access to research participants and data repositories. By engaging research organizations, the FACILITATE project can leverage their expertise and resources to enhance the robustness and relevance of its outcomes.

2.2 Clinicians

Clinicians, including physicians, nurses, pharmacists, and other healthcare professionals, are frontline providers of healthcare services. They play a crucial role in diagnosing and treating patients, managing chronic conditions, and promoting preventive care. Clinicians rely on access to reliable clinical data and evidence-based practices to deliver high-quality patient care and improve health outcomes.

Example: General practitioners, specialists (e.g., cardiologists, oncologists), Nurses, Pharmacists.

2.3 Patients

Patients are at the center of the healthcare system, and their perspectives, preferences, and experiences are critical for delivering patient-centered care. Patients seek access to safe, effective, and affordable healthcare services and medications to address their health needs. They play an active role in shared decision-making, self-management of chronic conditions, and advocating for their rights and interests in healthcare settings.

Example: Individuals receiving medical treatment or preventive care, Patients participating in clinical trials or research studies.

2.4 Regulatory bodies

Regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), are responsible for safeguarding public health by regulating the safety, efficacy, and quality of healthcare products and services. They establish and enforce regulations

governing clinical trials, drug approvals, manufacturing practices, and post-market surveillance to ensure patient safety and promote ethical research conduct.

Example: U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Pharmaceuticals and Medical Devices Agency (PMDA, Japan).

3. Needs assessment

A needs assessment serves as the compass guiding stakeholders through the complexities of planning, executing, and evaluating clinical studies. It provides a comprehensive understanding of the requirements, challenges, and objectives that must be addressed to ensure the success and ethical conduct of research endeavors.

The multifaceted nature of clinical research demands a nuanced approach to identifying and evaluating needs. From the perspective of sponsors, researchers, regulatory bodies, and participants, a needs assessment serves as the foundational step in developing strategies that maximize benefits while minimizing risks.

This section delves into the critical aspects of needs assessment, emphasizing its necessity in navigating the intricate pathways of clinical research. By illuminating the key objectives, challenges, and strategies for effective oversight, this needs assessment aims to equip stakeholders with the insights needed to make informed decisions and drive advancements in medical science.

3.1 Needs assessment: sponsors of research

In the realm of clinical research, sponsors play a pivotal role in driving innovation, funding studies, and bringing novel therapies to fruition. These sponsors, which often include pharmaceutical companies and research organizations, invest significant resources into the development and execution of clinical trials aimed at evaluating the safety and efficacy of new medical interventions.

At the core of these endeavors lies a crucial component: data. Clinical trial data not only form the foundation of evidence-based medicine but also hold immense potential to advance scientific understanding, improve patient care, and inform regulatory decisions. However, the traditional approach to data management in clinical trials has been somewhat siloed, with data often residing within the confines of sponsoring organizations, accessible only to select stakeholders.

In recent years, there has been a paradigm shift towards greater transparency and openness in data sharing, driven by a recognition of the collective benefits that stem from broader access to clinical trial data. This shift has led sponsors to reconsider their approach to data management, recognizing the value of returning data to participants and sharing it with the wider research community.

For sponsors of research, whether pharmaceutical companies or research organizations, the decision to share clinical trial data involves a delicate balance between maximizing the benefits of data sharing and minimizing the associated risks. Understanding these benefits and risks is essential to ensure that data sharing initiatives align with ethical principles and regulatory standards while advancing scientific progress and improving public health outcomes.

3.1.1 Potential Benefits of Data Sharing:

- Accelerated Scientific Progress: Sharing clinical trial data can expedite scientific advancements and contribute to improving public health by enhancing understanding of therapy safety and effectiveness. Secondary analyses of shared data have led to crucial discoveries, highlighting the inefficacy or risks of widely used interventions while improving clinical care.
- Increased Participant Contributions: Data sharing empowers clinical trial participants by expanding their contributions to generalizable knowledge about human health. Through

shared data, participants' involvement extends beyond the original trial outcomes, potentially facilitating additional discoveries and insights.

- Informed Decision-Making: Data sharing offers a more comprehensive view of intervention benefits and risks to society. This enables healthcare professionals and patients to make informed decisions about clinical care, leading to enhanced efficiency, safety, and effectiveness of medical interventions.
- Long-Term Public Health Benefits: Sharing clinical trial data has the potential to enhance public health outcomes by reducing adverse effects, minimizing ineffective interventions, and optimizing healthcare expenditure. Additionally, it fosters exploratory research, leading to new hypotheses and therapeutic approaches.

3.1.2 Risks of Data Sharing:

- Privacy and Confidentiality Concerns: Data sharing poses risks of privacy breaches and confidentiality violations, potentially harming participants socially or economically. Safeguarding participant privacy is crucial to mitigate these risks and build trust in data sharing initiatives.
- Misinterpretation and Distorted Analyses: Shared data might be subject to misinterpretation or distorted analyses, leading to inaccurate conclusions or claims of risk. Incorrect conclusions may deter appropriate therapy use, causing avoidable adverse effects and undermining public health.
- Undermined Incentives: Data sharing could undermine incentives for sponsors, investigators, and researchers to invest in developing and testing new treatments. Concerns about confidential information exposure, loss of intellectual capital, and inadequate recognition may deter future investment in clinical research.

3.1.3 Strategies for Responsible Data Sharing:

- Maximizing Benefits While Minimizing Risks: Sponsors recognize the ethical imperative to maximize the benefits of data sharing while minimizing associated risks. Aligning with principles of beneficence, sponsors prioritize the well-being of trial participants and society. International guidelines emphasize the importance of considering foreseeable risks and benefits before initiating a trial, ensuring the safety and rights of participants remain paramount.
- Respect for Participants: Respect for research participants is fundamental, requiring informed consent, privacy protection, and ongoing engagement. Sponsors must educate participants, provide information about study interventions, and protect their confidentiality during data sharing. Engaging participants and the public fosters trust and ensures transparency throughout the process.
- Building Public Trust: Public trust is essential for the integrity of clinical research and data sharing initiatives. Transparency, accountability, and fairness are key to fostering trust in the scientific process and trial results. Fair data sharing practices involve equitable treatment of participants and stakeholders, safeguarding intellectual property rights, and promoting understanding of the benefits and risks involved.
- Fair Data Sharing Practices: Fairness in data sharing entails recognizing the contributions of investigators, protecting intellectual property, and preventing unfair competition. By promoting fairness, sponsors incentivize participation in research, encourage innovation, and contribute to scientific advancement and improved patient care.
- Timing of Data Sharing: Determining when data should be shared is a critical consideration for sponsors. While acknowledging the complexity and variability of clinical trials, sponsors should adhere to evolving standards and best practices, ensuring that data sharing occurs in a manner that maximizes benefits while respecting the interests of all stakeholders.

3.2 Needs assessment: clinicians

Understanding the perspectives and requirements of clinicians is crucial for the successful implementation of healthcare innovations like the FACILITATE project. Through a detailed needs assessment, we gain valuable insights into clinicians' expectations and challenges in utilizing clinical trial data.

3.2.1 Return of Data: Incentives for Adoption

Clinicians play a pivotal role in returning individual data resulting from clinical trials to patients, primarily comprising relevant health records such as lab tests and imaging results. However, limitations may exist due to the study's protocol, often governed by the sponsoring entity's data analysis and publication processes.

A digital data platform encompassing all patient data is viewed favorably by clinicians, offering potential benefits for both practitioners and patients alike. They anticipate that such a platform would enhance their medical practice by providing comprehensive patient information, thereby facilitating better insight into patient conditions.

Machine-readable formats are preferred by clinicians for returning data, as they enable efficient analysis and integration into existing systems. Clinicians advocate for the accessibility of all relevant clinical trial data within Electronic Health Records (EHR), streamlining patient care and research efforts.

Despite recognizing challenges such as limited health literacy among participants, clinicians believe that with proper education and support, the impact can be mitigated. They express willingness to inform patients about the benefits and challenges of data return, emphasizing the importance of patient understanding and consent.

3.2.2 Secondary Use of Data: Incentives for Adoption

In addition to data return, clinicians are engaged in considering the secondary use of clinical trial data. They express comfort in explaining the pros and cons of secondary data use to patients and acknowledge its importance in advancing medical research.

While recognizing potential burdens in introducing secondary use information, clinicians emphasize its necessity for improving healthcare outcomes. They stress the importance of clear communication and patient involvement in the decision-making process.

Regarding their responsibilities within the legal framework, clinicians believe that introducing secondary use falls within their scope, highlighting the need for patient education and informed consent. They envision a hierarchical scheme of responsibility, starting from the Ministry of Health down to individual clinicians.

In summary, clinicians recognize the potential benefits of data return and secondary use in advancing medical research and improving patient care. Their insights provide valuable guidance for the development and implementation of the FACILITATE platform, ensuring alignment with clinician needs and preferences in the healthcare ecosystem.

3.3 Needs assessment: patients

In the context of the FACILITATE project's objectives, understanding the needs and preferences of patients and their caregivers regarding the Return of Data (RoD) process is paramount. To ensure the successful adoption and utilization of the RoD mechanism, it is crucial to incorporate features and functionalities that align with the participants' expectations and requirements. Here, we delve deeper into the essential criteria identified for the RoD process and explore the additional features deemed desirable by patients and caregivers:

3.3.1 Maximally Participant-Controlled Process:

- Participants' autonomy and agency in managing their data are fundamental. Participants must have clear and transparent information regarding the RoD process at the time of clinical trial (CT) enrollment and signing of the RoD Informed Consent Form (ICF). The participant/patient must have clearly and transparently presented process of RoD, before or at the time of CT enrolment and signing of RoD ICF, including any requirements, timelines, and potential limitations, risks or restrictions associated with the returned data, or interaction with the FACILITATE tool in the RoD process
- Participants should have the ability to revoke or amend their consent to RoD at any point during or after the CT.
- The participant/patient must have full control to disable or temporarily turn off any eventual notifications, alerting, or other proactive/push interaction features of the tool.

Desirable Features:

- Enabling participants to request and receive their data on-demand fosters a sense of ownership and facilitates their engagement in the research process.
- Structuring the returned data in standardized formats such as FHIR or SDTM, enhances its usability and interoperability, allowing participants to leverage it for various purposes beyond the clinical trial.

3.3.2 Fully Secure and Compliant Process:

- Compliance with personal data protection regulations is non-negotiable to safeguard participants' privacy and confidentiality throughout the RoD process.
- Implementing robust security measures and encryption protocols ensures that participants' data remains secure from unauthorized access or breaches.

Desirable Features:

- Additional security layers, such as multi-factor authentication and data encryption, can further bolster participants' confidence in the RoD platform's security posture.

3.3.3 Maximally Interactive Online Process:

- The RoD platform should provide a seamless and intuitive user experience, minimizing barriers to participation and engagement.
- Ensuring ease of navigation, clarity in instructions, and intuitive interface design enhances participants' comfort and confidence in interacting with the platform.

Desirable Features:

- Incorporating features that facilitate communication and collaboration between participants and researchers, such as chat support or virtual assistance, enriches the user experience and promotes active engagement.

By prioritizing these essential criteria and incorporating desirable features, the FACILITATE project aims to establish a patient-centric RoD process that not only meets regulatory standards but also empowers participants, fosters trust, and maximizes the value derived from clinical trial data.

The secondary use of data gathered through clinical trials can help ensure that the maximum value to human health is extracted from these data and potentially avoid unnecessary exposure to clinical trials. At the same time, the secondary use of clinical trial data can impact individual rights and interests, including the right to autonomy, data protection, privacy, and non-discrimination and they should be used with respects to participant rights and interest to build and consolidate participants trust

3.4 Needs assessment: regulatory bodies

Regulatory bodies play a critical role in safeguarding public health by ensuring the safety, efficacy, and quality of drugs and medical devices. However, the ever-evolving landscape of clinical research presents them with several challenges that hinder their ability to effectively fulfill this role. Understanding these needs is paramount for any initiative aiming to improve the regulatory environment. Here's an outside-in perspective on the key needs of regulatory bodies:

3.4.1 Data Scarcity and Limited Scope:

- **Limited access to long-term data**: Current clinical trials often lack long-term follow-up data, hindering regulators' ability to assess the long-term safety and efficacy of drugs and devices.
- **Absence of real-world evidence**: RWE, which provides insights into how treatments perform in real-world settings, is often unavailable or fragmented, making it difficult to gauge the effectiveness and potential side effects in diverse populations.
- **Narrow data focus:** Clinical trials often focus on specific patient cohorts and interventions, limiting the generalizability of findings and hindering the identification of potential risks in broader patient populations.

3.4.2 Data Fragmentation and Access Challenges:

- **Data silos and inconsistency**: Clinical trial data resides in scattered repositories with varying formats and standards, making it difficult to access, integrate, and analyze comprehensively.
- **Inefficient data access procedures**: Regulatory processes often involve lengthy data request procedures with limited access controls, impacting efficiency and raising potential data security concerns.
- **Burdensome data analysis**: Manual data analysis methods employed by many regulatory bodies are time-consuming and potentially prone to human error.

3.4.3 Transparency and Stakeholder Engagement:

- **Limited access to research protocols and data analyses:** Lack of transparency in trial design and data analysis practices can inhibit regulators' ability to fully assess the validity of submitted data.
- **Inadequate stakeholder engagement:** Insufficient communication and collaboration with researchers, patient groups and ethicists can lead to a disconnect between regulatory needs and research practices.

3.4.4 Streamlined Regulatory Processes:

- **Lengthy review times:** Current regulatory processes can be slow due to data access limitations and manual review procedures, delaying the availability of potentially life-saving treatments.
- **Limited post-marketing surveillance**: Traditional methods for post-marketing surveillance often lag in identifying emerging safety issues with new drugs and devices.
- **Inflexibility in adapting to new modalities:** Regulatory frameworks may struggle to keep pace with the rapid development of new drug delivery systems and medical devices. There is a need for evolving regulatory frameworks to adapt to the advancements in medical technology while maintaining patient safety.

3.4.5 Data Security and Privacy Concerns:

- **Potential data breaches and security risks:** Concerns regarding data security and privacy breaches in data sharing platforms can create hesitancy among regulators to rely on these platforms for decision-making. Robust cybersecurity measures and clear data governance frameworks are needed for data sharing platforms to ensure trust and encourage regulatory adoption.
- **Lack of clear data ownership and access controls:** Ambiguous data ownership structures and inadequate access control mechanisms can hinder trust in data integrity and regulatory confidence in utilizing the data. Establishing clear data ownership models and implementing granular access control mechanisms is necessary to address privacy concerns and ensure regulatory confidence in the data source.

By understanding these core needs of regulatory bodies, initiatives like FACILITATE can tailor their solutions to address these challenges and foster a more efficient, data-driven, and patient-centric regulatory landscape. The project's focus on data sharing, standardization, and transparency aligns with the needs identified in this assessment. Further research into the specific functionalities and data governance practices of FACILITATE would be necessary to determine how effectively it addresses these needs and builds trust with regulatory bodies.

4. Dependencies and potential barriers

Clinical research holds promise for advancing medical knowledge, yet it also encounters numerous potential barriers and dependencies that can hinder progress. Understanding these challenges is crucial for stakeholders to navigate the landscape effectively and ensure the success of clinical research endeavors.

4.1 Dependencies in Clinical Research

Collaborations and Partnerships
Partnerships among stakeholders are vital for success. These collaborations bring diverse expertise and resources. Effective collaboration requires clear communication and shared goals.

Regulatory Compliance
Adhering to regulations is foundational. Compliance ensures participant safety and valid study results. Non-compliance can lead to delays and fines.

Patient Engagement
Active patient involvement is crucial. Engaged patients provide valuable insights into study design and outcomes. Establishing meaningful engagement requires building trust and incorporating patient feedback.

Data Sharing and Transparency
Dependence on shared data promotes transparency and collaboration. Shared data allow for validation and meta-analyses. Concerns about data privacy and logistical challenges remain hurdles.

Professional Expertise
Clinical research relies on skilled professionals. Dependence on specialized knowledge is crucial for designing and analyzing trials. Investing in training ensures a competent workforce.

4.2 Potential Barriers in Clinical Research

Regulatory Complexity
Navigating regulatory requirements is a significant challenge in clinical research. Bodies like the FDA and EMA establish stringent guidelines, leading to lengthy approval processes, increased costs, and administrative burdens.

Financial Constraints
Financing clinical trials poses a challenge, especially for smaller research organizations. Costs for protocol development, patient recruitment, and data analysis can be substantial, deterring potential sponsors.

Patient Recruitment and Retention
Recruiting and retaining participants is a persistent challenge. Strict criteria, geographic dispersion, and competition with standard treatments hinder recruitment. Retaining participants requires continuous engagement and support.

Data Quality and Management
Ensuring data integrity and quality is crucial. Issues like missing data and errors can compromise study results. The increasing volume and complexity of clinical data pose challenges in managing and standardizing data.

Ethical Considerations
Balancing participant rights with scientific advancement requires attention to informed consent and privacy protection. Failure to uphold ethical standards can lead to legal repercussions and reputational risks.

Technological Advancements
While technological innovations offer opportunities, they also introduce challenges. Implementing and maintaining technology infrastructure for data collection and analysis requires significant investment and expertise.

In conclusion, clinical research faces a multitude of potential barriers and dependencies that can impact the progress and success of trials. From regulatory complexities and financial constraints to the need for patient engagement and technological advancements, stakeholders must navigate a complex landscape. Addressing these challenges requires a multifaceted approach, involving collaboration, innovation, and a commitment to ethical conduct. By identifying and understanding these barriers and dependencies, stakeholders can implement strategic solutions to overcome obstacles and drive forward the advancement of clinical research for the benefit of patients and society as a whole.

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