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CLINICAL TRIAL REGISTRIES AND REPORTING: PROGRESS, PITFALLS, AND PATH FORWARD

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ABSTRACT

Clinical trial registries are becoming a vital resource for advancing ethical integrity, accountability, and openness in scientific research. Clinical trial outcomes have historically been selectively published and underreported, undermining public confidence and scientific integrity. A crucial step in enhancing trial information accessibility and guaranteeing that trials are prospectively registered and publicly available was the creation of registries like ClinicalTrials.gov, EudraCT, and the Clinical Trials Registry–India (CTRI). Despite these advances, challenges persist in maintaining data quality. harmonization, and interoperability across registries. Variations in data fields, reporting standards, and compliance mechanisms among national and regional databases continue to hinder global consistency. Despite these advances, challenges persist in maintaining data quality. harmonization, and interoperability across registries. Variations in data fields, reporting standards, and compliance mechanisms among national and regional databases continue to hinder global consistency.

1. INTRODUCTION

Clinical trial is one of the most significant and accessible part of biomedical research. Transparency in clinical trial research is vital for ensuring scientific integrity and public trust. The lack of timely disclosure and selective reporting of results threatens both patient safety and welfare. Over half of all clinical trials conducted worldwide were historically never published in peer reviewed journals and many of those that were published often omitted key outcomes or adverse events data. This lack of transparency has been undermined the quality of biomedical research and contributed to selective reporting and bias. Ensuring transparency in clinical trials therefore not merely a procedural requirement but a core of ethical responsibility and trust.

Although clinical trials have developed and improved over time, leading to remarkable advancements in prevention, diagnosis, and therapy, there are still significant obstacles to overcome. Therefore, in order to reflect the drive in science and society to improve clinical research's efficiency, accountability, and transparency, significant alterations are required**.** In response to these challenges, the early 2000s marked a transformative era with the establishment of publicly accessible clinical trial registries. This article explores transparency in clinical trial and clinical trial registries evolution and their significant challenges aiming to find out future scope and directions. [(1,2)]

Clinical Trial registry: According to WHO clinical trials registry is the entity that houses the register, and is responsible for ensuring the completeness and accuracy of the information it contains, and that the registered information is used to inform health care decision making. A clinical trials registry is more than its database.

A suitable representative of the main sponsor of the trial is responsible for trial registration. The principal sponsor might or might not be the principal contributor. To guarantee that a trial is only registered once in a single register and in the fewest number of registers required to comply with applicable requirements, the responsible registrant should take all reasonable steps. Trials should be registered before participant recruitment.

The main purpose is to ensure transparency, accountability and public access to essential information regarding clinical trials including what interventions are being tested and what outcomes are being measured. [(3)]

Table 1: Example of WHO recognized trial registries

Registry Name	Region / Overseer	Year Established	Oversight Body
ClinicalTrials.gov	United States	2000	U.S. National Library of Medicine (NLM), NIH
EudraCT / EU Clinical Trials Register	European Union	2004 / 2011	European Medicines Agency (EMA)
CTRI (Clinical Trials Registry – India)	India	2007	Indian Council of Medical Research (ICMR) – National Institute of Medical Statistics
ISRCTN Registry	Global / UK-based	2000	BioMed Central / Springer Nature
Chinese Clinical Trial	China	2005	Chinese Academy of Medical Sciences

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Registry (ChiCTR)			
Japan Primary Registries Network (JPRN)	Japan	2005	National Institutes of Biomedical Innovation

Types of clinical registries:

The WHO Registry Network provides prospective trial registries with a forum to exchange information and work together to establish best practice for clinical trial registration.

The WHO Registry Network is composed of:

- Primary Registries
- Partner Registries
- Data Providers
- Registries working with the ICTRP towards becoming Primary Registries

Primary registers: Primary registries are those which meet specific criteria for content quality and validity, accesbility, Unique Identification, technical capacity and administration Primary registries meet the requirements of International Committee of medical journal editors (ICMJE).

Partner Registries meet the same criteria as Primary Registries in the WHO Registry Network (i.e. for content, quality and validity, etc) except they do not need to:

- Have a national or regional remit or the support of government
- Be managed by a not-for-profit agency
- Be open to all prospective registrants

All Partner Registries must also be affiliated with either a Primary Registry in the WHO Registry Network or an ICMJE approved registry. The ICTRP Secretariat is unable to receive data directly from Partner Registries.

It is the responsibility of Primary Registries in the WHO Registry Network to ensure that their Partner Registries meet WHO Registry Criteria.

Data Providers: Data Providers are responsible for a database that is used by one or more registries.

- Data Providers provide data to WHO for inclusion in the ICTRP Search Portal.
- The ICTRP will accept trial records from Data Providers if it is satisfied that those trial records have been created and managed in a manner that is consistent with the WHO Registry Criteria.

In some cases, the Data Provider will be the same organization as the Primary Registry.

Other registries

Any other registry that enters clinical trials into its database or that is working with ICTRP towards becoming a Primary Registry. [4,5]

Historical evolution: The historical evolution of clinical trial registries reflects a gradual but transformative shift toward transparency, accountability and ethical responsibility in biomedical research A crucial tool for finding all research pertaining to a major subject in a comparative effectiveness review (CER) is the registration of studies, especially randomized controlled trials (RCTs). Another possible instrument for evaluating SOR and SAR is registries. The formal idea of a registry was first proposed in the 1980s. [6]

In the United States, all efficacy drug trials for serious or life-threatening diseases and conditions conducted under FDA Investigational New Drug Application regulations had to be registered, according to the FDA Modernization Act of 1997, which also called for the establishment of ClinicalTrials.gov. Each record in Clinical trial.gov includes summary information on the study protocol, patient recruitment status and location of study site.

Effective July 2005, the International Committee of Medical Journal Editors (ICMJE) issued a policy outlining the requirements for an appropriate registry and requiring prospective trial registration as a condition of publication. A substantial increase in ClinicalTrials.gov registrations started in 2005 as a result of the ICMJE mandate.

World Health organization (WHO) Started a policy in 2006 requiring trial registration of all medical studies that test treatments on patients or volunteers and developed an international clinical trial registry platform., provide access to information regarding to on going and completed clinical trials. [7,8]

Challenges of clinical trial registries:

Clinical trial registries have emerged as crucial means for promoting scientific accountability and transparency on a global scale, but preserving their quality, consistency, and usability continues to be a challenge. Harmonization and interoperability are hampered by national variations in registry formats, data field definitions, and submission

procedures. Due to trial sponsors' frequent failure to promptly update recruitment status, protocol revisions, or outcomes, many registries suffer from missing, inconsistent, or out-of-date data. Data dependability is compromised by duplicate registrations across several registries and discrepancies between published and registered information. Uneven reporting standards are also a result of different enforcement strategies; in some nations, registration is required by law, while in others, compliance is voluntary. Registry systems are additionally strained by technical issues involving maintaining searchability, managing immense datasets, and interacting with publication databases.

Connecting registries to larger post-marketing and pharmacovigilance systems is another significant obstacle. Due to variations in data structure, privacy regulations, and the absence of typical patient identities, registries remain to have a limited connection with real-world evidence systems, while providing crucial pre-approval trial data. Research, regulatory, and pharmacovigilance databases must be able to communicate with one another in order for registry data to assist post-marketing surveillance, long-term safety monitoring, and health technology assessment. In most locations, this is currently a limited capability. Furthermore, maintaining data quality requires sufficient financial resources, knowledgeable human capital, and regular monitoring by international organizations like the WHO. Therefore, despite the significant increase in transparency brought about by clinical trial registries, issues with data harmonization, compliance enforcement, and integration with actual safety monitoring systems still restrict their full potential. [9,10]

Path forward

The path forward for clinical trial transparency requires moving beyond registries as static repositories toward building a fully integrated, patient centered and globally harmonized ecosystem of accountability. One of the most urgent priorities is establishing global harmonization of reporting standards. An objective long advocated by international organizations such as the WHO and ICMJE. [11,12] Despite substantial progress, inconsistencies across national and regional databases such as ClinicalTrials.gov, EU CTR, CTRI and ChiCTR limit comparability and slow progress in evidence synthesis [13]. Harmonized reporting frameworks with standardized data elements, definitions and timelines would allow trial results to be aggregated seamlessly across jurisdictions, supporting global evidence-based medicine. Such an approach aligns with proposals for international guidelines on trial registration and result reporting, reinforcing the idea that transparency should not depend on geography but rather be recognized as a universal ethical imperative.

The next frontier lies in the integration of real-world evidence (RWE). Linking trial records with safety signals, electronic health records and registry based observational studies would enable continuous monitoring of therapeutic performance across the full product life cycle, from pre-clinical development to post marketing. This would create a dynamic ecosystem where efficacy, safety and real-world utility are studied not in isolation but in cumulative continuity [14,15]. Such integration ensures that patients contributions extend beyond trial participation to inform robust evidence that safeguards public health.

In essence, the future of trial registries lies not in incremental reform but in building a life cycle, global and patient centered transparency ecosystem. A system that enforces compliance, integrates real world data, harmonizes across jurisdictions and translates clinical evidence into accessible formats for all stakeholders. This ambitious vision would transform registries from compliance checklists into the backbone of trustworthy, reproducible and equitable medical science.

2. CONCLUSION

Clinical trial registries have significantly advanced the culture of openness and accountability in clinical research by making trial protocols and results publicly accessible. However, the persistence of data gaps, inconsistent reporting practices, and weak enforcement mechanisms indicates that transparency remains a work in progress. Achieving harmonization among registries under the WHO International Clinical Trials Registry Platform (ICTRP) and enforcing compliance through stronger regulatory oversight are critical next steps. The future of registry systems lies in their integration with post-marketing surveillance, electronic health records, and real-world evidence networks, enabling continuous monitoring of safety and efficacy throughout a product's life cycle. Strengthening global collaboration, adopting uniform data standards, and ensuring timely updates will transform registries from mere documentation platforms into dynamic systems that safeguard scientific integrity, protect public health, and reinforce trust in biomedical innovation.

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