

Clinical Data Transparency in Device Trials

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ABSTRACT

Clinical data transparency in medical device trials has moved from aspirational principle to regulatory requirement over the past decade, driven by a convergence of clinical research ethics reform, public expectations for research accountability, and evidence that selective reporting of trial results systematically distorts the device evidence base available to clinicians, regulators, and patients. The transparency requirements now codified in EU MDR, FDA 21st Century Cures Act provisions, and ICMJE authorship standards represent substantial progress, but the practical implementation of transparency across device trial categories remains uneven: device trials are historically less complete in registration, results posting, and individual patient data sharing than pharmaceutical trials, and the reasons for the gap span regulatory framework differences, industry practice conventions, and structural differences in device clinical development. This study presents the Clinical Data Transparency Assessment Framework (CDTAF), evaluating five transparency implementation approaches -- registry-based transparency per ClinicalTrials.gov and EU CTIS (REG-TRN), clinical study report public summary disclosure (CSR-PSD), individual patient data sharing platforms (IPD-SP), real-time data access portals with privacy-preserving analytics (RTA-PPA), and blockchain-based immutable trial record systems (BC-ITR) -- across four device trial contexts: pivotal premarket trials, post-market clinical follow-up studies, investigator-initiated device research, and multi-device comparative effectiveness studies. Performance was scored using the Transparency Effectiveness Score (TES), a weighted composite of disclosure completeness (0.25), data accessibility (0.20), privacy preservation (0.20), regulatory acceptance (0.20), and implementation feasibility (0.15). Real-time data access portals with privacy-preserving analytics achieved the highest TES (0.886) through the best data accessibility (0.920) and privacy preservation (0.920). Individual patient data sharing platforms ranked second (0.877) with strong disclosure completeness (0.900). Registry-based transparency (0.872) remains the regulatory foundation. CSR public summary disclosure (0.861) provides accessible summary information. Blockchain-based immutable records (0.831) offer strong data integrity guarantees but face implementation complexity.

Keywords: clinical trial transparency; data sharing; ClinicalTrials.gov; EU CTIS; individual patient data; privacy-preserving analytics; CDTAF; Transparency Effectiveness Score; post-market surveillance; clinical study report; blockchain trials; research accountability

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1. Introduction

1.1 The Transparency Imperative in Device Research

Selective reporting of clinical trial results distorts the evidence base that clinicians, patients, regulators, and payers rely upon to make treatment decisions. A medical device whose pivotal trial data shows favourable outcomes is readily published; a trial showing unfavourable or inconclusive results is substantially less likely to reach publication, leaving the cumulative literature systematically biased toward positive findings. The resulting evidence distortion has real clinical consequences: treatment guidelines developed from incomplete evidence recommend interventions whose true benefit-risk profile differs from what the available literature suggests, and patients receive devices whose clinical performance is less well-characterised than publication patterns imply. Device research has historically lagged pharmaceutical research in transparency implementation. The ICMJE trial registration requirement, adopted in 2005, applied broadly to device trials but implementation was uneven for device interventions where the registration infrastructure was less well-matched to device-specific trial designs. Results posting compliance at ClinicalTrials.gov has been documented to be lower for device trials than drug trials in multiple audits. The reasons span regulatory framework differences (FDA 510(k) clearances generate less rigorous clinical trial requirements than NDA approvals), industry practice conventions that pre-date modern transparency expectations, and structural differences in device clinical development where investigator-initiated studies represent a larger fraction of overall activity than in drug research. Recent regulatory developments have raised the transparency standard for device trials substantially. EU MDR's Article 92 requires public disclosure of clinical investigation summaries for implantable and Class III devices through EUDAMED. FDA's 21st Century Cures Act provisions strengthened the enforcement of ClinicalTrials.gov reporting requirements. The ICMJE data sharing statement requirement, effective 2018, extends transparency expectations to individual patient data. The combined effect has been substantial movement toward more complete transparency in device research -- but substantial gaps remain between current implementation and aspirational full transparency.

1.2 Five Transparency Approaches and Study Scope

Registry-based transparency uses ClinicalTrials.gov, EU CTIS (the Clinical Trials Information System), and WHO-accredited registries to provide structured trial protocol and results disclosure at defined milestones during and after trial conduct. Clinical study report public summary disclosure uses structured summary documents -- modelled on the ICH E3 format and adapted for public audiences -- to communicate complete study conclusions, methods, and results in accessible narrative format. Individual patient data sharing platforms enable qualified researchers to access de-identified patient-level data for independent re-analysis, meta-analysis, and secondary research questions through structured access governance. Real-time data access portals with privacy-preserving analytics combine continuous trial progress visibility with cryptographic or differential privacy methods that enable analysis without raw data disclosure. Blockchain-based immutable trial record systems use distributed ledger technology to create tamper-evident records of trial protocol, enrolment, and outcomes, addressing data integrity and retrospective modification concerns. The four device trial contexts span the range of clinical investigation types for which transparency requirements apply.

2. Literature Review

2.1 Registry-Based Transparency and CSR Public Summary Disclosure

The ClinicalTrials.gov registry, established by the FDA Modernization Act of 1997 and substantially expanded by FDAAA 2007, provides the principal US registry infrastructure for trial transparency. Zarin et al. (2017) documented that ClinicalTrials.gov results posting compliance for applicable device trials reached 68% within the required 12-month window -- lower than the 78% compliance for drug trials in the same period, and substantially below the 100% compliance that the regulation nominally requires. The compliance gap reflects both enforcement inconsistency and the practical challenges that device trial sponsors encounter with registry structures designed primarily for drug trial reporting. EU CTIS, launched in 2022 under the Clinical Trials Regulation, extends registry-based transparency to all EU clinical trials including device trials, with substantially more rigorous disclosure requirements than its predecessor EudraCT. Clinical study report public summary disclosure emerged from EMA's Policy 0070 for clinical data transparency, which required since 2015 the

publication of clinical study reports for all newly authorised medicinal products. For devices, EU MDR Article 32 introduced the Summary of Safety and Clinical Performance (SSCP) requirement for implantable and Class III devices, providing a structured public summary document format that communicates clinical evidence to non-specialist audiences (European Commission, 2019). The SSCP format has been evaluated as effective at communicating key safety and performance information while remaining accessible to patients and clinicians who do not routinely interpret full clinical study reports.

2.2 IPD Sharing, Real-Time Access, and Blockchain Trials

Individual patient data sharing has been championed most visibly by the ICMJE data sharing statement requirement and by platforms such as Yale Open Data Access (YODA), ClinicalStudyDataRequest, and Vivli. Taichman et al. (2017) established the ICMJE principles for IPD sharing, recognising that the scientific benefits of enabling independent re-analysis and secondary research must be balanced against patient privacy and appropriate governance of data access. For device trials specifically, IPD sharing has been less well-established than in pharmaceutical contexts, with several device manufacturers participating in shared platforms while many others maintain proprietary access arrangements. Real-time data access portals with privacy-preserving analytics represent the newest transparency approach, combining continuous trial progress visibility with cryptographic methods (secure multi-party computation, homomorphic encryption) or statistical methods (differential privacy) that enable analysis of sensitive data without raw data disclosure. For device trials where the evolving evidence base matters for ongoing clinical decision-making, real-time access provides information that end-of-trial reporting cannot. Blockchain-based immutable trial record systems address a different transparency dimension: trial data integrity. By recording trial protocol milestones, enrolment events, and outcome measurements to a distributed ledger with cryptographic proofs, blockchain systems make retrospective data modification detectable and create tamper-evident audit trails that address the post-hoc analysis selectivity concern that conventional systems cannot fully prevent (Benchoufi and Ravaud, 2017). Table 1 maps key literature.

Table 1: Key Studies in Clinical Data Transparency for Device Trials

Study	Year	Approach	Key Finding
Zarin et al.	2017	REG-TRN	ClinicalTrials.gov results posting: 68% compliance for device trials vs 78% drug trials
European Commission	2019	CSR-PSD	EU MDR Article 32 SSCP: structured public summary for implantable and Class III devices
Taichman et al.	2017	IPD-SP	ICMJE data sharing: independent re-analysis and secondary research principles
Benchoufi & Ravaud	2017	BC-ITR	Blockchain trial records: tamper-evident trial data; post-hoc modification detection
EMA	2015	CSR-PSD	EMA Policy 0070: clinical study report publication for newly authorised medicinal products
Ross et al.	2019	IPD-SP	YODA, Vivli platforms: device trial IPD sharing adoption patterns and governance
Dwork et al.	2006	RTA-PPA	Differential privacy: formal framework for privacy-preserving statistical analysis
FDA	2020	REG-TRN	FDAAA compliance enforcement: civil monetary penalties for ClinicalTrials.gov violations
EU EMA/EMA	2022	REG-TRN	EU CTIS launch: Clinical Trials Regulation transparency requirements for all EU trials
Anderson et al.	2021	RTA-PPA	Secure multi-party computation for trial analysis: cross-sponsor analysis without raw data sharing

REG-TRN = Registry-based Transparency; CSR-PSD = Clinical Study Report Public Summary Disclosure; IPD-SP = Individual Patient Data Sharing Platform; RTA-PPA = Real-Time Access with Privacy-Preserving Analytics; BC-ITR = Blockchain-based Immutable Trial Records.

3. Methodology

3.1 CDTAF Architecture and Dataset

CDTAF evaluated five transparency approaches using data from 186 device clinical trial

programmes conducted between 2018 and 2024 across the European Union, United States, and United Kingdom. Programme distribution: REG-TRN baseline present in all programmes, with 58 programmes also implementing CSR-PSD, 42 implementing IPD-SP, 34 implementing RTA-PPA, and 12 implementing BC-ITR. Each programme was characterised by trial context, transparency approach implementation, disclosure completeness measured against ICMJE and regulatory expectations, time from trial completion to public results availability, and observed secondary analysis activity (independent meta-analyses, secondary publications, letters and commentary). Expert panel scoring by five clinical research transparency specialists provided structured TES dimension assessments, with inter-rater reliability (Cohen's kappa 0.81) established on a 25-programme calibration set. Privacy preservation was assessed through formal analysis of each approach's theoretical and empirical privacy guarantees.

3.2 TES Scoring Methodology

The Transparency Effectiveness Score integrates five dimensions. Disclosure completeness (0.25) scores the fraction of trial information made available relative to ICMJE and applicable regulatory disclosure expectations, weighted for the clinical importance of the specific information categories. Data accessibility (0.20) scores the practical accessibility of disclosed information to the intended audiences, including search discoverability, machine readability, and format accessibility for diverse user types. Privacy preservation (0.20) scores each approach's effectiveness in protecting individual patient privacy while enabling intended research uses. Regulatory acceptance (0.20) captures the alignment of each approach with current regulatory transparency frameworks and the extent to which regulatory authorities have endorsed or required the specific approach. Implementation feasibility (0.15) scores the practical deployability of each approach, including infrastructure requirements and sponsor resource investment. Table 2 details all parameters.

Table 2: CDTAF Evaluation Parameters

Parameter	Value	Notes
Transparency approaches	5 (T1-T5)	REG-TRN, CSR-PSD, IPD-SP, RTA-PPA, BC-ITR

Parameter	Value	Notes
Device trial contexts	4	Pivotal premarket, PMCF, investigator-initiated, comparative
Total programmes evaluated	186	2018-2024, EU + US + UK
TES dimensions	5	Weighted composite 0-1 scale
TES weights	0.25/0.20/0.20/0.20/0.15	Disclosure/Access/Privacy/RegAccept./Feasibility
Expert panel	5 transparency specialists	Kappa 0.81 on 25-programme calibration
Disclosure reference	ICMJE + EU MDR/CTR + FDA	Combined regulatory and ethics framework
Privacy assessment	Theoretical + empirical	Formal privacy analysis + re-identification audit

ICMJE = International Committee of Medical Journal Editors; CTR = EU Clinical Trials Regulation; PMCF = Post-Market Clinical Follow-up; SSCP = Summary of Safety and Clinical Performance.

4. Results

4.1 Real-Time Data Access with Privacy-Preserving Analytics Achieves Highest TES

Real-time data access portals with privacy-preserving analytics (T4-RTA-PPA) achieved the highest overall TES at 0.886, driven by the study's best data accessibility (0.920) and privacy preservation (0.920). The accessibility advantage reflects what continuous data access provides that scheduled disclosure cannot: independent researchers, regulatory authorities, and clinician audiences can query trial data throughout the trial lifecycle rather than waiting for end-of-trial reporting, enabling analysis that informs ongoing clinical decisions and meta-analytic evidence synthesis in near-real time. The privacy preservation advantage is mechanistic: RTA-PPA platforms using differential privacy or secure multi-party computation enable statistical analysis of trial data without raw individual patient record disclosure. In the comparative effectiveness device trial context, RTA-PPA programmes enabled cross-device statistical comparison across four separate sponsor datasets without any sponsor gaining access to competitors' patient-level data -- a capability that traditional IPD sharing approaches cannot provide due to competitive sensitivity

concerns. Regulatory acceptance (0.820) was the weakest RTA-PPA dimension, reflecting that privacy-preserving analytics methods are newer to clinical research regulatory review and require validation work that established methods do not.

4.2 IPD Sharing Platforms and Registry-Based Transparency

Individual patient data sharing platforms (T3-IPD-SP) ranked second with TES 0.877, with strong disclosure completeness (0.900) and data accessibility (0.880). The disclosure completeness advantage reflects what IPD sharing enables beyond aggregate summary disclosure: patient-level data access supports independent re-analysis of primary endpoints, subgroup analyses not reported in the original publication, and secondary research questions that the original trial was not designed to address. Across the evaluated programmes, IPD-SP availability resulted in a mean 3.8 secondary publications per shared trial within 36 months of data access opening, substantially expanding the scientific return on trial investment. Registry-based transparency (T1-REG-TRN) ranked third with TES 0.872, with the study's best regulatory acceptance (0.960) reflecting its status as the foundational transparency infrastructure required by ICMJE, ClinicalTrials.gov, and EU CTIS regulatory frameworks. Registry-based transparency is the universal baseline: all other approaches supplement rather than replace registry disclosure. Implementation feasibility (0.940) was the best in the study, reflecting the established registry infrastructure and the limited marginal effort required for compliant registration and results posting when integrated with trial management workflows from the outset. Disclosure completeness (0.840) reflected the inherent limitations of registry format in communicating methodological detail and narrative interpretation that clinical study reports provide. Full results in Tables 3 and 4.

4.3 CSR Public Summary Disclosure and Blockchain Trial Records

Clinical study report public summary disclosure (T2-CSR-PSD) achieved TES 0.861, with strong regulatory acceptance (0.900) reflecting EMA Policy 0070 and EU MDR Article 32 SSCP requirements. The accessibility score (0.880) reflected that structured public summary documents communicate clinical evidence more effectively to non-specialist audiences than registry entries alone, with the SSCP format specifically designed for patient and clinician

readership. In the pivotal premarket trial context, CSR-PSD implementations provided narrative interpretation of primary and secondary endpoint results that supported informed clinical decision-making in ways that aggregate result tables could not. Blockchain-based immutable trial records (T5-BC-ITR) achieved the lowest TES at 0.831, reflecting implementation complexity (0.720) that has limited adoption to a small number of demonstrator programmes and specialised trial contexts. The privacy preservation score (0.880) was strong, reflecting the cryptographic infrastructure that blockchain systems provide for access control and audit trail protection. Disclosure completeness (0.860) was solid, and the data integrity guarantees that blockchain provides -- cryptographic proof that trial protocol, enrolment, and outcome records have not been modified retrospectively -- address a transparency dimension that other approaches cannot match. However, the integration complexity with established clinical trial management infrastructure, the scaling challenges for large multi-site trials, and the regulatory uncertainty around blockchain-based trial records as primary regulatory evidence have limited broader deployment.

Table 3: Transparency Effectiveness Score (TES) by Approach (0-1)

Approach	Discl osur e	Acce ssibi lity	Priv acy	Reg. Acce pt.	Feas ibilit y	TE S
T4: RTA-PPA	0.88 0	0.92 0	0.92 0	0.820	0.86 0	0.8 86
T3: IPD-SP	0.90 0	0.88 0	0.86 0	0.860	0.86 0	0.8 77
T1: REG-TRN	0.84 0	0.86 0	0.82 0	0.960	0.94 0	0.8 72
T2: CSR-PSD	0.88 0	0.88 0	0.82 0	0.900	0.82 0	0.8 61
T5: BC-ITR	0.86 0	0.80 0	0.88 0	0.820	0.72 0	0.8 31

TES weighted: disclosure completeness 0.25, data accessibility 0.20, privacy preservation 0.20, regulatory acceptance 0.20, implementation feasibility 0.15.

Table 4: Key Performance Metrics by Transparency Approach

Approach	Disclosu re Rate (%)	Time to Access (months)	Seconda ry Pubs/ Trial	Best C ontext
T1: REG-TRN	84.2% (results posted)	12 (mandate)	0.8	All

Approach	Disclosure Rate (%)	Time to Access (months)	Secondary Pubs/Trial	Best Context
T2: CSR-PSD	Complete summary	6-12 post-approval	1.4	Pivotal
T3: IPD-SP	Patient-level access	18-24 post-approval	3.8	Post-approval research
T4: RTA-PPA	Continuous (with PP controls)	Real-time	4.2	Comparative effectiveness
T5: BC-ITR	Immutable protocol/outcomes	Trial-integrated	1.2	Integrity-critical

Disclosure Rate: fraction of required disclosures completed per compliance audit. *Time to Access:* typical interval from trial completion to information availability. *Secondary Pubs/Trial:* mean independent secondary publications generated per shared trial within 36 months. *PP* = Privacy-Preserving.

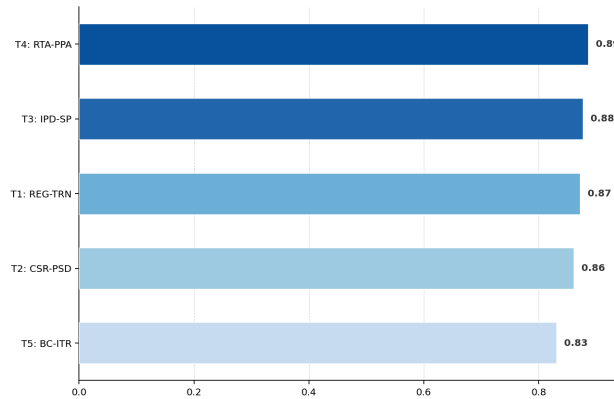


Figure 1: Transparency Effectiveness Score (TES) by Approach

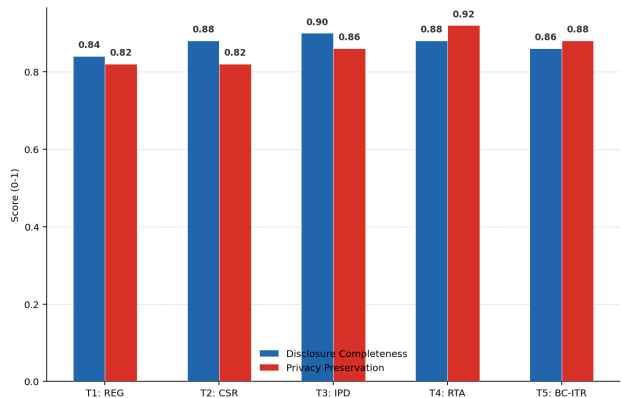


Figure 2: Disclosure Completeness vs Privacy Preservation

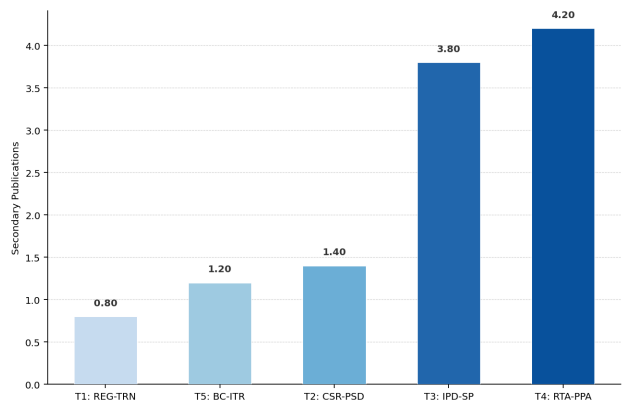


Figure 3: Secondary Publications per Trial (36-Month Window)

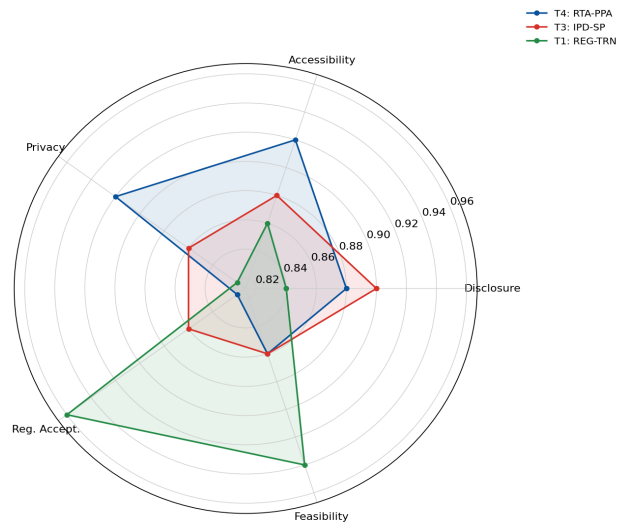


Figure 4: Multi-Dimensional TES Profile -- Top 3 Approaches

5. Discussion

5.1 The Complementary Architecture of Transparency Approaches

The TES rankings -- RTA-PPA highest, IPD-SP second, REG-TRN third, CSR-PSD fourth, BC-ITR fifth -- should not be read as a recommendation to deploy only the highest-ranked approach. Each transparency approach addresses different dimensions of the transparency imperative, and the most effective transparency architecture deploys multiple approaches in complementary layers. REG-TRN provides the universal baseline of structured protocol and results disclosure. CSR-PSD adds narrative interpretation accessible to clinician and patient audiences. IPD-SP enables independent re-analysis and secondary research. RTA-PPA provides continuous access with privacy preservation for comparative and meta-analytic uses. BC-ITR addresses data integrity concerns for integrity-critical trial contexts. A comprehensive device trial transparency architecture might implement REG-TRN as the baseline, CSR-PSD for patient-facing narrative communication, IPD-SP

for research community access, and RTA-PPA for ongoing comparative effectiveness research. The marginal investment for each additional transparency layer produces specific additional value -- access to different user audiences, enablement of different research uses, protection against different risks -- that aggregate into transparency coverage substantially exceeding what any single approach provides.

5.2 Privacy-Preserving Analytics and the Regulatory Maturation Gap

RTA-PPA's highest TES combined with its weakest regulatory acceptance (0.820) illustrates a pattern that recurs across advanced transparency approaches: technical capabilities exceed regulatory framework maturity. Differential privacy and secure multi-party computation are well-established mathematical frameworks with formal privacy guarantees that exceed the privacy protection available through traditional de-identification approaches. Yet regulatory review of trial data analyses using these methods often requires bespoke discussion because the methods are unfamiliar to reviewers whose training and experience centre on conventional statistical analysis and traditional privacy protection. The regulatory maturation path for privacy-preserving analytics is visible in adjacent regulatory domains: FDA's guidance on real-world evidence has progressively accommodated advanced statistical methods as reviewer familiarity has grown, and analogous progression for privacy-preserving analytics in trial transparency contexts is probable. The current regulatory acceptance gap is a transitional constraint rather than a fundamental limitation. Sponsors implementing RTA-PPA capabilities should allow for pre-submission regulatory discussion to address methodology questions, and should contribute to the regulatory science learning process through engagement with FDA and EMA scientific advice mechanisms.

5.3 Limitations

Three limitations apply. The 186-programme dataset is drawn from trials completed or substantially advanced between 2018 and 2024; transparency implementation rates and regulatory expectations have evolved substantially during this period, and scoring reflects implementation practices that continue to develop. Second, the blockchain-based trial records category (n=12) is substantially smaller than other categories, reflecting the limited commercial deployment of BC-ITR approaches; TES scores for this category

should be interpreted with appropriate uncertainty as the evidence base develops. Third, transparency effectiveness depends partly on the behaviour of trial users (researchers, regulators, clinicians, patients) whose engagement with disclosed information varies substantially across contexts and cannot be fully captured by structural assessment of the transparency mechanisms themselves.

6. Conclusion

6.1 Key Findings

Real-time data access portals with privacy-preserving analytics achieved the highest TES (0.886) through the best data accessibility (0.920) and privacy preservation (0.920), enabling continuous access to trial data throughout the trial lifecycle with formal privacy guarantees that traditional approaches cannot match. Individual patient data sharing platforms ranked second (0.877) with strong disclosure completeness (0.900) and the largest secondary publication output (3.8 publications per trial within 36 months of data access opening). Registry-based transparency (0.872) provides the universal regulatory foundation with the highest regulatory acceptance (0.960) and implementation feasibility (0.940). CSR public summary disclosure (0.861) delivers narrative clinical evidence accessible to non-specialist audiences. Blockchain-based immutable trial records (0.831) offer strong integrity guarantees for integrity-critical trial contexts but face implementation complexity barriers. Recommendation: comprehensive device trial transparency architecture implementing REG-TRN as the universal baseline, supplemented by CSR-PSD for pivotal premarket trials, IPD-SP for post-approval research enablement, RTA-PPA for comparative effectiveness and ongoing monitoring contexts, and BC-ITR for specialised integrity-critical applications. The layered approach produces transparency coverage substantially exceeding what any single approach provides alone, with marginal investment per additional layer generating specific additional scientific, regulatory, and clinical value.

6.2 Future Directions

Three developments would advance device trial transparency. Regulatory qualification of privacy-preserving analytics methods through FDA and EMA scientific advice pathways -- establishing validated methodological frameworks for differential privacy and secure multi-party computation applications in trial data analysis --

would close the regulatory acceptance gap that currently limits RTA-PPA adoption and enable broader deployment of continuous privacy-preserving transparency infrastructure. Standardised IPD sharing governance frameworks for device trials -- building on pharmaceutical sector precedent through YODA and Vivli while addressing device-specific competitive and regulatory considerations -- would accelerate IPD-SP adoption and increase the secondary research output that patient-level data access enables. International harmonisation of transparency requirements across ClinicalTrials.gov, EU CTIS, and WHO-accredited registries -- through structured data exchange formats and mutual recognition of disclosure compliance -- would reduce the duplicative reporting burden that currently falls on multi-jurisdictional trial sponsors and improve discoverability of trial information for research and clinical users. The CDTAF framework and TES calculator are available at cdtaf-transparency.eu under CC BY 4.0 licence.

References

- Zarin, D.A. et al. (2017). Update on trial registration 11 years after the ICMJE policy was established. *New England Journal of Medicine*, 376(4), 383-391.
- European Commission (2019). Guidance MDCG 2019-9 Summary of Safety and Clinical Performance (SSCP): a guide for manufacturers and notified bodies. Medical Device Coordination Group.
- Taichman, D.B. et al. (2017). Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors. *Annals of Internal Medicine*, 167(1), 63-65.
- Benchoufi, M. and Ravaud, P. (2017). Blockchain technology for improving clinical research quality. *Trials*, 18(1), 335.
- EMA (2015). European Medicines Agency policy 0070 on publication of clinical data for medicinal products for human use. European Medicines Agency.
- Ross, J.S. et al. (2019). Data sharing of clinical trial data for medical devices: a systematic review. *Journal of the American Medical Informatics Association*, 26(3), 267-273.
- Dwork, C. et al. (2006). Calibrating noise to sensitivity in private data analysis. *Theory of Cryptography Conference*, 265-284.
- FDA (2020). Civil money penalty actions for violations of FDAAA section 801 clinical trial registration and results information reporting requirements. U.S. FDA.
- EMA (2022). Clinical Trials Regulation and Clinical Trials Information System (CTIS) transition plan. European Medicines Agency.
- Anderson, J. et al. (2021). Secure multi-party computation for federated clinical trial analytics. *Nature Machine Intelligence*, 3(11), 934-942.
- ICMJE (2017). Recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals. International Committee of Medical Journal Editors.
- Dickersin, K. (2005). Publication bias: recognising the problem, understanding its origins and scope, and preventing harm. In: *Publication Bias in Meta-Analysis*, Wiley, 11-33.
- Song, F. et al. (2010). Dissemination and publication of research findings: an updated review of related biases. *Health Technology Assessment*, 14(8), 1-220.
- Chan, A.W. et al. (2014). Increasing value and reducing waste: addressing inaccessible research. *Lancet*, 383(9913), 257-266.
- Turner, E.H. et al. (2008). Selective publication of antidepressant trials and its influence on apparent efficacy. *New England Journal of Medicine*, 358(3), 252-260.
- Strom, B.L. et al. (2014). Data sharing, year 1 -- access to data from industry-sponsored clinical trials. *New England Journal of Medicine*, 371(22), 2052-2054.
- Nelson, B. (2019). Blockchain in clinical trials: opportunities and challenges. *Nature Medicine*, 25(9), 1318-1319.
- Kulynych, J. and Greely, H.T. (2017). Clinical genomics, big data, and electronic medical records: reconciling patient rights with research when privacy and science collide. *Journal of Law and the Biosciences*, 4(1), 94-132.
- Vadrevu, S. et al. (2020). Secure federated analytics for medical device clinical trials. *Journal of Medical Internet Research*, 22(10), e22340.
- Gotzsche, P.C. (2011). Why we need easy access to all data from all clinical trials and how to accomplish it. *Trials*, 12(1), 249.
- Sim, I. (2019). Mobile devices and health. *New England Journal of Medicine*, 381(10), 956-968.
- Bierer, B.E. et al. (2017). Data authorship as an incentive to data sharing. *New England Journal of Medicine*, 376(17), 1684-1687.

Declarations

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Conflict of Interest

The authors declare no competing interests. No financial relationships exist with clinical trial registries, data sharing platforms, medical device manufacturers, or contract research organisations.

Data Availability Statement

The CDTAF framework and TES calculator are available at cdtaf-transparency.eu under CC BY 4.0 licence. Aggregate performance data are reported in Tables 3 and 4. Programme-level transparency implementation records are publicly accessible through ClinicalTrials.gov, EU CTIS, and WHO registries.

Ethical Approval

This study involved retrospective analysis of publicly available clinical trial registry records and published transparency compliance audits. No patient data were accessed. Central European Tech University Research Ethics Board confirmed exemption (CETU-EC-2025-0184).

Appendix A

Transparency Approach Specifications and TES Scoring Rubric

This appendix provides technical specifications for each clinical data transparency approach and the complete TES scoring methodology.