The Clinical Data Governance Checklist (CDGC): Human-Centered Infrastructure for Ethical Routine Outcome Monitoring in Digitally Mediated Psychotherapy

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Abstract

Routine outcome monitoring (ROM) in digitally mediated psychotherapy increasingly occurs within complex data ecosystems involving structured assessments, unstructured clinical data, system metadata, and artificial intelligence (AI)–derived outputs that traverse multiple vendors and jurisdictions. These developments expose governance gaps in consent transparency, data-flow visibility, and lifecycle responsibility, while also interacting with persistent human and organizational barriers to ROM adoption (Jonášová et al., 2025; Cecil et al., 2026). This paper presents the *Clinical Data Governance Checklist (CDGC)* as practice-ready, human-centered governance infrastructure to support ethical and learning-oriented ROM in outpatient psychotherapy settings. The CDGC is a reflective governance tool designed to support visibility, proportional decision-making, and trust rather than regulatory compliance or performance evaluation. It is organized as eleven practitioner-facing sections addressing purpose limitation, consent, data mapping, scope and proportionality, AI-enabled features, access, retention, and accountability. For analytic clarity, these sections are discussed as seven governance domains that make explicit how checklist prompts work together to support ethical ROM, consent portability, and clinician psychological safety. Designed for reuse during platform adoption, renewal, and system change, the CDGC enables clinics and individual practitioners to align consent language with actual data practices, increase transparency within distributed vendor ecosystems, and sustain trust in digitally and AI-mediated care (Cooney-Waterhouse et al., 2025; Effiong et al., 2026).

Keywords. routine outcome monitoring, digital governance, psychotherapy, informed consent, artificial intelligence, ethics

Introduction and Problem Framing

Digital tools are now embedded across psychotherapy practice, including electronic health records, ROM platforms, messaging systems, and scheduling tools, with AI-enabled features increasingly integrated into these environments (Cecil et al., 2026). As a result, clinical data encompass not only structured measures, but also unstructured text, communication logs, metadata, and AI-assisted summaries or analytics. These data often traverse multiple vendors, subprocessors, and jurisdictions, creating gaps between consent disclosures and actual data practices (Brückner et al., 2025).

At the same time, ROM remains unevenly implemented in psychotherapy. Clinicians cite time pressure, workflow disruption, emotional unreadiness to receive feedback, fear of evaluation, and concerns about punitive data use as barriers to meaningful engagement with outcome monitoring (Jonášová et al., 2025). These challenges illustrate that governance gaps are not solely technical or legal, but also relational and cultural.

Governance approaches that emphasize compliance or security alone may overlook how data practices shape trust, clinical judgment, and the therapeutic alliance. In digitally mediated and AI-supported contexts, governance that undermines clinician autonomy or client understanding risks eroding the conditions required for effective care (Cooney-Waterhouse et al., 2025). The Clinical Data Governance Checklist (CDGC) is proposed as a clinic-level governance instrument designed to support visibility, reflection, and proportional decision-making in everyday practice.

Importantly, the CDGC is not intended as a legal, regulatory, or compliance audit. It functions as a practical governance aid that helps clinicians and organizations document awareness, clarify boundaries, and revisit decisions as systems evolve, without introducing surveillance or punitive oversight (Effiong et al., 2026).

Objective and Scope

The objective of this paper is to position the CDGC as practice-ready governance infrastructure that translates governance-gap analysis into clinic-controllable workflows aligned with ethical ROM implementation. The checklist explicitly addresses unstructured and AI-derived data, distributed vendor ecosystems, consent portability, and clinician psychological safety (Brückner et al., 2025; Jonášová et al., 2025).

The CDGC is intended for outpatient psychotherapy and behavioral health settings, including agencies, group practices, and solo practitioners. It emphasizes governance activities within clinical and organizational control—such as consent communication, workflow boundaries, vendor awareness, and access limitation—rather than jurisdiction-specific regulatory compliance. Its lightweight design supports use in small or resource-limited practices without specialized governance infrastructure (Effiong et al., 2026).

Governance Principles

Relational protection and the therapeutic alliance

Digital governance must protect trust and the relational foundation of psychotherapy, particularly when ROM data or AI-derived signals are introduced into care (Cooney-Waterhouse et al., 2025).

Purpose limitation and clinical judgment

Digital systems should support, not substitute for, clinical judgment. Outputs such as scores, summaries, or automated insights must be governed as advisory and contextual rather than determinative of care decisions (Cecil et al., 2026).

Consent portability and transparency

Consent must reflect actual data practices—including cross-border processing, secondary uses, and AI-mediated features—and remain adaptable as systems and platforms evolve (Brückner et al., 2025).

Proportional access and lifecycle awareness

Access to clinical data should be role-limited and proportionate, and derived data should be handled with documented awareness across retention and withdrawal processes (Effiong et al., 2026).

Non-punitive outcomes governance

ROM data should support learning and care improvement rather than performance surveillance, preserving clinician psychological safety and professional autonomy (Jonášová et al., 2025).

The CDGC Domains

The *Digital Clinical Data Governance Checklist* is structured as eleven practitioner-facing sections designed to support concrete, clinic-level reflection on digital data practices. For analytic clarity, these sections are discussed in this manuscript as seven governance domains. This grouping does not reorganize or replace the checklist itself; rather, it makes explicit how specific checklist sections function together to support ethical routine outcome monitoring (ROM), consent portability, and clinician psychological safety.

Clinical integration and purpose limitation

(Checklist Sections 1 and 5: Purpose and Role of Digital Tools; Use and Secondary Use)

These sections prompt clinics to clarify the purpose of each digital tool used in practice and to define how outcome and related data may and may not be used. Governance at this level emphasizes that digital systems support, but do not replace, professional judgment, and that ROM data are used to inform care rather than to evaluate or discipline clinicians. Grouping these sections highlights governance of *meaning and use*, protecting the therapeutic alliance and reinforcing non-punitive outcomes governance (Jonášová et al., 2025).

Consent language and client communication

(Checklist Section 2: Informed and Ongoing Consent)

This domain focuses on ensuring that consent processes reflect real data practices in clear, plain language. Checklist prompts emphasize disclosure of what information is collected, why it is collected, and how it supports care, while treating consent as an ongoing process rather than a one-time event. Explicit attention to consent portability is essential as platforms introduce new features or integrations that alter data flows over time (Brückner et al., 2025).

Data inventory and proportionality

(Checklist Section 4: Scope and Proportionality)

This section supports reflection on what data are collected, including optional inputs, unstructured information, and system-generated data, and whether such collection remains reasonable and proportionate to clinical purpose. Governance at this level helps prevent mission creep, ensuring that data practices remain aligned with therapeutic goals rather than platform defaults or vendor incentives.

Data-flow mapping and jurisdictional awareness

(Checklist Sections 3 and 7: Data Mapping and Visibility; Data Location and Cross-Border Access)

These sections work together to support awareness of how clinical data move through digital systems, including storage locations, backups, integrations, subcontractors, and cross-border access. Governance is grounded in visibility rather than technical control, enabling more accurate consent disclosures and accountability within distributed vendor ecosystems (Effiong et al., 2026).

Access, confidentiality, and role limitation

(Checklist Section 8: Access and Confidentiality)

This domain addresses who may access clinical data and under what conditions. The checklist prompts reflection on access by clinical, administrative, and technical personnel, emphasizing role-limited and proportionate access to protect confidentiality, trust, and clinician psychological safety in the use of ROM data (Cooney-Waterhouse et al., 2025).

Lifecycle awareness for derived and AI-assisted data

(Checklist Sections 6 and 10: AI and Automated Features; Records and Retention)

These sections address governance challenges introduced by AI-enabled and automated features, as well as unstructured and derived data. The checklist emphasizes high-level understanding of inputs and outputs, reinforces that AI supports rather than replaces clinical judgment, and ensures that derived data are included in retention, deletion, and withdrawal planning. Grouping these sections highlights proportional responsibility rather than technical explainability, aligning governance with real-world clinical capacity (Cecil et al., 2026; Effiong et al., 2026).

Vendor governance and ongoing accountability

(Checklist Sections 9 and 11: Security Incidents; Review and Accountability)

This domain brings together reflection on vendor responsibilities, incident awareness, and the need for periodic review of digital practices. Governance is treated as recurring clinical work rather than a one-time policy task, particularly as vendors update functionality, terms of service, or subprocessor arrangements. This approach supports shared accountability while maintaining clinic-level visibility and control (Effiong et al., 2026).

Method and Development Process

The CDGC is a practice-oriented governance tool rather than a validated scale or audit framework. It supports structured reflection on digital clinical data practices and is intended for periodic reuse during system adoption, renewal, or change. Completion of the checklist produces documented awareness and review cycles rather than compliance scores, aligning governance activity with clinical realities and capacity constraints (Effiong et al., 2026).

Practical Applications

The CDGC is designed for direct use in routine clinical and organizational workflows rather than as a stand-alone policy document. Clinics may apply the checklist at key decision points such as ROM platform selection or renewal, onboarding of clinicians, introduction of new digital or AI-enabled features, or scheduled governance reviews. For individual practitioners and small practices, the checklist can function as a structured self-review tool that supports clearer consent conversations, more confident integration of ROM data in sessions, and greater awareness of how digital systems shape documentation and data flows.

For larger clinics or agencies, the CDGC provides a shared vocabulary for discussing governance across clinical, administrative, and technical roles without requiring specialized governance or legal expertise. In both contexts, documenting checklist reflection helps make implicit assumptions about data use explicit, supporting transparency for clients and psychological safety for clinicians. By embedding governance reflection into everyday practice, the CDGC supports ethical ROM implementation that remains responsive to system change while preserving clinical judgment and the relational foundations of care.

Box 1

Example Vignette: Completing One Checklist Section in Practice

Checklist Section 6: AI and Automated Features

A small outpatient psychotherapy clinic uses a digital documentation platform that offers an optional AI-assisted feature for drafting session summaries based on clinician-entered text. The feature is marketed as a time-saving tool and can be enabled or disabled at the individual clinician level.

When completing Section 6 of the CDGC, the clinic first documents that an AI-assisted feature is present within the system and confirms that its use is optional. Clinicians review, at a high level, the inputs used by the feature (free-text notes entered by the clinician during or after sessions) and the outputs generated (a suggested narrative summary draft). It is recorded that AI-generated text is never automatically saved to the clinical record and is always reviewed, edited, or discarded by the clinician before inclusion.

The checklist notes that the AI feature is used solely to support documentation efficiency and not for assessment, diagnosis, or treatment recommendations. Clinicians explicitly affirm that the feature does not replace professional judgment. Consent materials are reviewed to ensure that clients are informed, in general terms, that digital systems used in their care may include automated or AI-assisted documentation support, without implying automated clinical decision-making.

Finally, the clinic records an action note to revisit this checklist section if the vendor introduces new AI-enabled features or changes how the existing feature operates. Through this process, the clinic establishes documented awareness, proportionate boundaries for AI use, alignment with clinical judgment, and consent transparency—without requiring technical explainability or extensive governance infrastructure.

Evaluation and Reflective Indicators

The Clinical Data Governance Checklist does not prescribe performance metrics or evaluative benchmarks. Instead, it supports the use of *reflective indicators* that signal whether governance practices are visible, understood, and revisited over time. Such indicators may include client understanding of digital data use, completeness of checklist review, visibility into vendor data practices, patterns of routine outcome monitoring uptake, clinician experience and psychological safety, responsiveness to data-withdrawal or deletion requests, and awareness of data incidents or near-misses. Used reflectively rather than punitively, these indicators support learning, transparency, and trust while avoiding surveillance or performance management dynamics (Jonášová et al., 2025; Effiong et al., 2026).

Positionality Statement

The author approaches this work from a practice-informed perspective, with experience in psychotherapy and applied research in digital health contexts. The development of the Clinical Data Governance Checklist was shaped by engagement with clinicians, small practices, and organizations navigating the ethical use of digital tools, routine outcome monitoring, and emerging AI-enabled features in care delivery. This standpoint informs an emphasis on reflective, proportionate governance that supports trust and clinical judgment rather than compliance-oriented or technically prescriptive approaches.

Limitations and Future Directions

This paper presents the Clinical Data Governance Checklist as a practice-oriented governance tool rather than an empirically validated intervention. Accordingly, it does not report outcome data demonstrating the checklist's effects on routine outcome monitoring uptake, consent comprehension, clinician experience, or client outcomes. The CDGC is designed to support reflective governance across diverse practice contexts, and its impact will depend on how clinicians and organizations interpret, apply, and revisit its prompts over time. Additionally, while the checklist is intended to be adaptable across jurisdictions, it does not address jurisdiction-specific legal requirements and should not be construed as comprehensive regulatory guidance. Future research could examine how use of the CDGC shapes clinician experience, client understanding of digital data practices, and governance capacity in specific settings, as well as its integration alongside formal regulatory or organizational frameworks.

Conclusion

The Clinical Data Governance Checklist provides a clinic-ready, non-punitive approach to governing digital clinical data that aligns consent, data visibility, and clinical use in digitally mediated psychotherapy. By explicitly linking governance domains to checklist sections, the CDGC preserves its practitioner-focused design while supporting analytic clarity. **Ethically, treating data governance as an ongoing clinical responsibility—rather than a background technical or compliance task—helps ensure that the expansion of digital and AI-enabled tools in psychotherapy strengthens trust, preserves clinician judgment, and respects the relational conditions on which effective care depends.**

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Appendix A

Digital Clinical Data Governance Checklist (CDGC)

The *Digital Clinical Data Governance Checklist* (Hansen, 2026) is a practitioner-facing reflective tool developed by Holistic Research Canada and licensed under the Creative Commons Attribution 4.0 International License (CC BY 4.0). This appendix provides a brief overview of the checklist's structure (the eleven section headings). The full, fillable checklist can be downloaded from the Holistic Research Canada post titled *Introducing the Clinical Data Governance Checklist*.

1. Purpose and role of digital tools
2. Informed and ongoing consent
3. Data mapping and visibility
4. Scope and proportionality
5. Use and secondary use
6. AI and automated features
7. Data location and cross-border access
8. Access and confidentiality
9. Security incident awareness
10. Records and retention

11. Review and accountability

The checklist is intended to be completed through documented reflection and periodic review rather than as a compliance or audit instrument. The full checklist is available from **Holistic Research Canada** as a downloadable file via *Introducing the Clinical Data Governance Checklist* (holisticresearchcanada.ca), or by scanning the provided QR code.