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Beyond the Patient: The Role of Clinical Data Managers in Mediating Human Identity in Modern Trials

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ABSTRACT

Clinical Data Managers (CDMs) are in a strategic position to mediate patient identity during the vascular trial turning subjective clinical inputs into standardized data structures. CDMs in the context of data-intensive environments make essential decisions that relate to edit checks, reconciliation of the timestamps, and codification practice that forms the way trial subjects are digitally represented. The aim was to investigate the role of clinical data managers in building, transformation and de-identification of patient identity in vascular studies through data handling and standardization practices. A qualitative research design was adapted where semi-structured interviews were used among CDMs (n=10), cardiac professionals, trial coordinators, and imaging analysts in order to examine the use of identity mediation in vascular trials. The information sources were query logs, audit trails and discrepancy reports. Thematic analysis was used to determine the major patterns that include identity curation, data abstraction, and algorithmic governance. Different viewpoints were guarantees by purposive sampling. The results show that CDM in vascular trials play a significant role in shaping patient identity wherein raw clinical data (ABI values, ECG data, and imaging results) are converted into standard formats. The clinical visibility, safety evaluation, and eligibility depend on their choices in data normalization, alignment of timestamps and adverse event coding. Such identity mediation issues concerns of re-identification, algorithmic bias, and depersonalization of governance of posthuman data. The research reinstates CDM as identity mediators in vascular trials and underlines their ethical involvement in data management and suggests patient-oriented leadership to retain clinical complexity and humanity.

KEYWORDS: Clinical Data Management, Vascular Trials, Endovascular Data, Identity Curation, Clinical Data Managers, Data Standardization.

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INTRODUCTION

Clinical data management (CDM) is described as a key activity in clinical research that coordinates quality clinical study data and statistically valid data that are collected are at acceptable cost with regulatory compliance[1]. The clinical data manager within the vascular trials especially dealing with Peripheral Artery Disease (PAD) is an important epistemic player in the human subjectivity being transformed into analyzable clinical data[2]. World Health Organization-ICTRP (International Clinical Trials Registry Platform) report indicate that by mid-2024, ICTRP encompasses approximately 944,000 interventional trials in 229 countries[3,4]. In 2024, the clinical data management systems (CDMS) market was estimated to reach USD 3.11 billion and by 2034 it is estimated to go up to USD 8.90 billion[5]. Electronic case report forms (eCRFs) are designed, relational databases are constructed and validated, automated edit checks are implemented, queries are initiated and locking database processes implemented by CDMs[6]. This role is further complicated in the context of vascular trials when CDMs need to be able to interpret unclear clinical indicators[7]. In such transformations, the CDMs facilitate the process of the subject identity construction of lived clinical presentations into abstracted and harmonized data structures.

Accurate alignment in time amongst imaging reports, pharmacologic treatments (e.g. heparin administration), and clinical incidents including thrombosis or hemorrhage are vital to vascular trials[8]. The process of CDMs needs to harmonize uncoordinated data provided by the electronic health records, procedure records, and radiology systems to provide a coherency in terms of time[9]. An error in alignment between the time of drug administration and the time of the event can result in classifying adverse events erroneously, which have a direct impact on primary trial outcomes[10]. CDMs mandated with enforcing de-identification measures that eliminate explicit and implicit identifiers, and substitute them with pseudonymous subject's identifiers[11]. However, more recent implementations of deep learning algorithms revealed that it is possible to re-identify members of ostensibly anonymized datasets, especially when it comes to hospital imaging records[12]. despite using sophisticated algorithms, such as deep learning applied to hospital X-rays, have been able to re-identify individuals identified in allegedly anonymized healthcare data[13]. Aided by the Good Clinical Data Management Practices (GCDMP), the CDMs in vascular trials are much more than mere custodians; in the moral, technical, and ontological conversion of humans into regulatory-compliant data objects.

Despite the central role clinical data managers in organizing and protecting patient data in vascular trials, their dynamic contribution in constructing human identity by data transformation is under-researched. There is no detailed theoretical basis of grasping the ethical implication of identity mediation in clinical data managers, especially in the context of data pseudonymization

and the risk of re-identification[14]. The study lack the operational limitation of the concurrent match of clinical timestamps of real-time vascular occurrences, recognized to be a problem in reconciliation in cardiovascular trials[15]. Limited empirical studies exist concerning the threat of re-identification in vascular-trial data, indicating that even when biometric images or ECG data have been de-identified there remains still threat of re-identification[16]. Moreover, the regulation of CDM practices is conventionally analyzing in the compliance and technical efficiency rather than the critical or posthuman analysis that interrogates the remaking of the human body as information through the digital infrastructures[17]. This study bridges the gaps by preempting CDM as a proactive identity mediator, using post humanist and sociotechnical lenses to understand their work, and putting the process of human-data transformation returns.

The current study provides a novel insight on the role of CDM as a participant but also as an identity curator within contemporary clinical research. This study examines how CDMs mediate clinical subjectivity in contemporary vascular trial, and the conversion of duplex ultrasound data into standardized stenosis values. This study reveal the impact of data practices on building, diminishing, and controlling human identity in technological mediated vascular research. The study aim was to examine the impact of clinical data managers on the building, transformation, and de-identification of patient identity in vascular trials by data handling and standardization practices. The study objectives were to examine the mediating role of clinical data managers in vascular clinical trials identity. It aimed at investigating the ethical and governance consequences of reducing vascular clinical observations to depersonalized datasets. Moreover, it was aimed to examine the impact of posthuman governance constructions on the redefinition of identity with the help of digital records and algorithm systems within the environment of vascular trials.

LITERATURE REVIEW

2.1 Clinical Data Management (CDM) in Modern Trials

Clinical Data Management (CDM) has developed into a refined system that includes advanced electronic and AI-based systems as opposed to manual ones that were paper-based[18]. In the early days, clinical trial data were documented on paper case report forms (CRFs), which meant that the data had to be manually transcribed and verified at various levels[19]. However, Pestronk et al. (2021) discussed that CDMs started to exploit the value of real-time data entry, forbidden edits with or without built-in and audit trails to enhance the quality and integrity of the data[20]. While, Balch et al. (2023) illustrated that multi-site access, centralized monitoring and quick sharing of data have also been facilitated by the incorporation of cloud-based platforms[21]. Although, Banach et al. (2022) study emphasized that trials have evolved to be more and more complicated and data-intensive, the role of CDMs is to become more one of a regulatory adherence, metadata management, and protocol optimization[22].

In cardiovascular trials, CDMs play the role in forming what may be called a cardiac online nature of a patient [23]. Islam et al. (2020) explored that CDM manage the processing of raw physiological signals like electrocardiograms (ECGs) to the form of data that can be analyzed (signal cleaning which involves noise elimination, baseline, and artifact removal)[24]. The laboratory values such as BNP and NT-proBNP are standardized by converting them to units and standardizing them to the global trial sites by using values in the central lab[25]. However, Tcheng et al. (2021) highlighted another essential role is timestamp alignment between devices and vendors; any differences in this context can cause the distortion of the temporal relationships between interventions and outcomes[26]. Moreover, Prasanna et al. (2024) identified that CDMs reconciliate intermodal datasets as well, such as between ECG and lab outcomes, drugs given, or adverse events, informed by logic rules which have a direct impact on efficacy and safety endpoint integrity[27].

2.2 Emergence of Clinical Data Managers

Clinical Data Managers (CDMs) play influential roles in trials involving vascular outcomes and, to a larger extent, in trials that are performed to evaluate the cardiovascular outcomes[28]. Ehidiamen & Oladapo (2024) discussed that the design of edit checks can be named as one of such decisions that guarantee the real-time validation of incoming data[29]. An edit check would be initiated should a systolic blood pressure entry be less than 60 mmHg or an adverse event (e.g. stroke) is recorded without a corresponding timestamp or intervention record meeting that event[30]. Concurrently, Kamble et al. (2025) highlighted that coding and mapping decisions which can be achieved with the help of MedDRA and WHO Drug Dictionary Enhanced (WHO-DD) demand that CDMs use standard terms to designate commonly used clinical language in variables[31]. Regarding this, such terms as cold leg may be fragmented into limb ischemia or neuropathy, depending on the situation and the history of the narration[32]. These decisions can affect control over interpretations of safety signals, regulatory reports and judgment in the court.

The CDMs role is even more important in the multi-vendor and increasingly AI-driven research setting where interoperability of data, its normalization and de-identification of neutrality and ethically charged processes[33]. Heiberg et al. (2022) identified hat synchronization errors may threaten the integrity of data under a multi-vendor vascular trial involving separate ECG interpretation software and laboratory platforms and a centralized EDC system[34]. As an example, when ECG vendor records an event of bradycardia at 10:05 a.m. and EDC records heparin administration at 10:30 a.m., a reconciliation process should be carried out to ensure that cause and effect relationships are not misclassified[35]. However, Lee et al. (2025) mentioned that CDMs logic reconciliation and audit trail help identify the lack of values, patient ID disparities, and time differences and trigger data clarification requests (DCRs) to vendors[36]. Furthermore, the value of central labs (e.g., NT-proBNP) have different units (e.g., pmol/L vs. pg/mL), and to make this comparable across the sites, CDMs may need to use global mapping protocols[37]. CDMs tightly determine the structure and cross-linkage of physiological signals, laboratory values, as well as clinical events to abstract trial subjects into regulatory-compliant globally disreputable identities.

2.3 Access, Ethics, and Control of Patient Data

The role CDMs have in modern cardiovascular clinical trials goes further than mere data oversight due to their intermediation of patient identity construction by virtue of their interaction with de-identified albeit highly structured physiological data[38]. It is

especially apparent in how the constant cardiac telemetry, BNP levels and ECG waveform data are stored and organized. Asher (2023) study identify the direct identifiers are eliminated by de-identification, both the fidelity and granularity of cardiac signal (trend of left ventricular ejection fraction) lead to indirect re-identification, particularly in combination with device-specific metadata[39]. However, Isibor (2024) explored that CDMs are at a precarious ethical crossroad as they need to balance the regulatory requirements of privacy (e.g., GDPR pseudonymization requirements or HIPAA Safe Harbor) with the integrity and clinical utility of the cardiovascular information[40]. Making granularity smaller would guard against privacy, to examine security signs especially in borderline arrhythmic occurrences or biomarker changes that suggest latent cardio toxicity[41].

The structure data field governance of cardiac trials directly influences the extent of secondary analysis and commercial reuse without patient knowledge, and in most cases[42]. To provide an example, the waveform-coded ECG data and organized BNP response traces (after removing them out of their original trial context) become objects re-used in training an AI model or calibration of a prediction device[43]. However, Kubick (2021) illustrated that CDSMs not only structure these fields, but also provide standards such as CDISC SDTM or ODM formats, which implicitly feature future interoperability and reuse[44]. Moreover, Spithoff et al. (2025) discussed that governance layer, which can be mostly governed by sponsors or data brokers, can largely circumvent the agency of participants particularly in instances where re-use provisions are pasted in general consent terminologies[45]. This brings up significant issues regarding data sovereignty since high-fidelity cardiovascular profiles reused to create non-open-source algorithms to detect arrhythmia or generate drug-device interactions models.

2.4 Posthuman Governance

In vascular trials where high frequency biometric information such as ECG waveforms, duplex imaging, and biomarkers are crucial, CDMs are the epistemic designers of the manner in which human identities are documented, organized and eventually analyzed[46]. Adedinsewo et al. (2022) explored that replacement of paper-based clinical records by digitized, shifted the role of CDMs into a central mediating variable, to translate non-homogeneous clinical information into homogeneous fields[47]. A patient with an ABI of 0.92 that falls in the borderline classification of the PAD diagnostic criteria would be automatically classified as a non-pathology to exclude them of additional imaging or therapeutic follow-up in the electronic case report form (eCRF)[48]. Chaiter et al. (2024) highlighted that choices are data capture logic redefining the categorization of patients and which physiological manifestations are regarded as clinically meaningful[49]. Moreover, Horinaka et al. (2025) illustrated that duplex ultrasound measurements to assess the stenosis of the arteries should be converted into categorical values including less than half, or more than three quarters[50].

These mediated identities have significant implications in the algorithmic governance. The existing biases in biomedical research can be recreated by data standards and cleaning rules[51]. Reddy et al. (2023) discussed that population-based thresholds of BNP are in many cases based on majority demographic populations, and this may be an underrepresentation of cardiovascular risk in ethnic underrepresented populations[52]. By implementing such norms in all bodies, CDMs would unwillingly promote clinical hierarchies in the name of neutrality. Cardiovascular safety signals are put into structured fields, the decisions regarding what is recorded, e.g., QT prolongation and not subjective dizziness, identify trial-relevant adverse events[53]. Although, Morain et al. (2022) identified issues of ethics are not abstract in nature but how a particular identity is made visible to trial sponsors and regulators by specific decisions made with respect to data design[54].

2.5 Conceptual Framework

2.5.1 CDM as Identity Curators

Clinical Data Managers (CDMs) also have a decisive, yet unseen impact on the construction of human identity in contemporary clinical trials[55]. Being the curators of identity, they encode the subjective experiences of patients into data points of the form of fields, forms, and coded variables that become the official account on a biomedical identity of a participant. CDMs mediate what gets represented, accentuated or suppressed in the lived experience of a person through choices made regarding standards of data, query resolution, and the categorization of a symptom. This change is an indicator of the Classification Theory of Bowker and Star, which posits that classification systems are not orientation of reality, but its creation[56]. Through the identification of the way illness, response, and deviation are documented, CDMs have a direct role in analysis of the trial participant identity as a data subject. Foucault theory of Biopower sheds light on processes within an institution, which transforms bodies into quantifiable objects, and thus provides control and regulation[57]. Schweinar et al. (2024) discussed that CMDs operationalize this in the form of imposing uniformity, disambiguating ambiguity, and purifying patient data, or compiling it into a standardized computerized form[58]. Their work does not only have the effect on scientific validity but it also determines the object of the patient in the form of a clinical object, which is quantified, categorized, and comparable. CDMs play the role of translations between the biological self, and the regulatory-scientific sets that determine what is considered evidence, reinforcing the modern trial as dependent on data as the main manifestation of human health[59].

2.5.2 Identity Mediation Pipeline in Vascular Trials

Clinical Data Managers (CDMs) influence the way a vascular-trial participant turns into a uniform data identity through converting the heterogeneous clinical inputs into structures that can be analyzed[2]. In a carotid revascularization study like CREST-2, e.g., raw vascular data consist of duplex and ultrasound velocity measurements, CT angiography, Antiplatelet therapy, plus narrative of the adverse events logs, documented by the researchers[60]. In the process of cleaning, discordant readings include the peak systolic velocity (PSV) measured as 240 and 120 cm/s on the two visits even though both visits had the same imaging[61]. Cas et al. (2024) emphasized that CDMs validate source document and rectify unsound pertinent units, or dispel protocol volcanism, determining which description of the physiology of the participant is authentic[62]. The data is then normalized and the data across modalities is standardized, e.g. the volumes of plaque in a CT angiography are coded into consistent cubic-millimeter formats and translations such as, e.g. Aspirin low-dose are encoded using dosage dictionaries[63]. Subgroup analysis, e.g., CREST-

2 downstream inferences that determine risk of stroke in patients with 70% or above stenosis of the Vessel, are completely based on this curated identity[64]. Theofilis et al. (2024) illustrated that CDMs do not jettison plaque morphology correctly, or they do not correct adjustments in PSV thresholds between machines, their resulting phenotypes able to confuse hazard ratios and subgroup interpretations[65]. Therefore, CDMs provide epistemic gateway of the technical choices that decide the degree to which the clinical account of an individual participant in a vascular-trial can be faithfully represented in the digital character (See Figure 1).

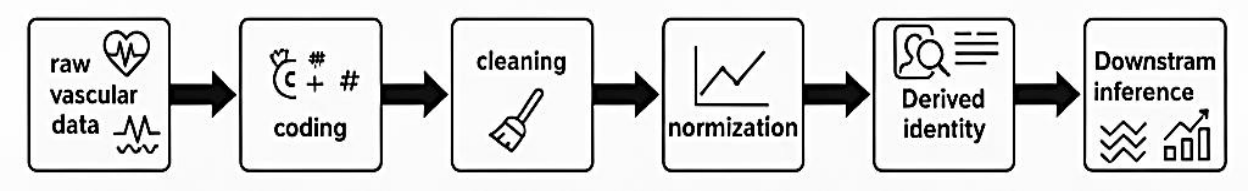

Figure 1: Identity Mediation Pipeline in Vascular Trials

METHODOLOGY

3.1 Research Approach

This study employs primary qualitative research design to investigate how CDMs mediate human identity in the digital infrastructures of vascular clinical trials. The study was carried out via semi-structured interviews to concentrate on the lived experience and interpretive practice of CDMs. The qualitative design enables a delicate comprehension of the data practices integration with ethical, cultural, and posthuman issues in biomedical research. This method is appropriate that tends to underestimate the issue of human mediation of infrastructure connected with vascular clinical data and the underlying assumptions on identity.

3.2 Participants

The participants involved in the study were (n=10) respondents included clinical data managers, cardiac professionals who had direct involvement in the design of a trial. Purposive sampling was used to select CDM and cardiac professionals so that different views were represented. The cardiac practitioners provided opinion on the impact of these data processes on clinical interpretation, operational and patient safety. The inclusion criteria were that the participants should have a minimum of three years of experience in a vascular or cardiovascular trial, and participate in a data cleaning, coding, or reconciliation workflow. As the main participants, CDMs were chosen, and to triangulate the interpretations of the influence of the data transformation on clinical sense, cardiac professionals and imaging analysts were also included.

3.3 Interview Procedure

The interviews were semi-structured and took about 45-60 minutes. They were held through video conferencing systems that were secure, and were audio-taped with the consent of the participants. The interview guide was built iteratively using the existing literature about clinical data governance, identity mediation, and posthuman theory. The questions were about the decisions related to data standardization, the reconciliation of timestamps, practices of de-identification, and the ethical conflicts that are observed during the everyday work on CDM. All the interviews were transcribed word-to-word and the anonymization done before analysis.

3.4 Data Collection

The primary information source used to collect the required data on the influence of CDM in the human identity mediation of a vascular clinical trial covers a wide array of qualitative and institutional data. They also examined query logs, audit trails and discrepancy reports to monitor the resolution of inconsistencies, timestamps inspection, and measurement standardization across sites by CDMs. Semi-structured interviews with CDMs, trial coordinators, cardiac professionals and imaging-core analysts allowed capturing pragmatic knowledge relating to ambiguous vascular data interpretation and how the information can be converted into structured analytical identities.

3.5 Data Analysis

In this research, thematic analysis was used to investigate the mediating role of CDMs in clinical vascular trials in converting patient experiences into structured data in the form of datasets. All the relevant literature and actual data were coded into common themes which were identity curation, data abstraction, algorithmic governance, and ethical implications. These themes were refined over and over again to show patterns in the interaction of how CDMs constitute digital identity, decisions, and interact with sociotechnical and posthuman profound frameworks in contemporary vascular systems. In order to increase the level of analytic rigour, first coding was done, followed by constant comparison to refine the codes. Raw transcripts and other supporting documentation (audit trails, query logs) were reviewed against themes. The highest level of analytic saturation was achieved when the appearance of new conceptual categories was not noticed. To record interpretive decisions, reflexive memoing was also sustained.

3.6 Ethical considerations

This research follows ethic guidelines of confidentiality, consent and responsible use of data deals with identity mediation by using clinical data. The semi-structured interviews were all done with the informed consent and maintained anonymity to the participants, more so Clinical Data Managers (CDMs). The information on patients was gathered in anonymized and aggregated format and no efforts were made to identify personal identities. The study critically reflects on the ethical considerations of data abstraction which includes the possibility of re-identification, algorithm bias, and identity misrepresentation.

RESULTS

4.1 Identity Mediation in practice of CDM

Respondents always indicated that their work was associated with the active perpetual decision-making regarding patient information conversion to structured trial data. Clinical Data Managers (CDMs) pointed out that the raw clinical data; imaging results, physiological data, and narrative descriptions of adverse events, do not often find their way to trial databases in their pure form. These contributions are instead subject to numerous stages of refinement, authentication and reorganization before they are adopted as final documents. A few CDMs described that identity mediation is done in instances where they ascertain which form of conflicting information to make authoritative. One participant stated:

"It is not uncommon to have two values of the same visit one on the site and one on the imaging core. It is up to me to determine which one will represent the patient on the trial".

Respondents said this was particularly widespread in vascular studies; with measures of ankle-brachial index (ABI), duplex ultrasound velocities, or ECG outputs potentially having device or operator variation. CDMs had reported fixing such discrepancies with reference to protocol thresholds, site queries, or with set validation rules. These behaviors, as the participants state, have a direct impact on the recording of the clinical status of a participant.

Another participant noted:

"Once the data is encrypted, it is the version that becomes the patient. Whatever could not fit the model is no longer in sight"

CDMs also characterized intermediating identity in terms of practices of coding. The free-text clinical descriptions provided by investigators were often mapped with standardized dictionaries. To illustrate, one of the participants stated that the descriptive words like the discomfort in legs or the cold extremity were typically transformed into the pre-established adverse event categories, based on protocol definitions and the options provided. The language could be subtle, and yet the system needs one code. Such decision remains on the patient record throughout the analysis.

The participants underlined that such decisions were not some exceptional cases but the normal practice of their day. A few of the CDMs observed that the accumulating impact of minor choices resolving inconsistencies, implementing corrections, sealing queries, and so on generated a consistent digital portrait of every participant. This profile was further applied in safety analysis, eligibility analysis, and endpoint analysis. In interviews, the CDMs defined their role as stewardship and not data passiveness. Although they did not call themselves manipulators of the information about patients, they still admitted that their choice influenced the way subjects were depicted in the trial system. To sum it up, as one of the respondents concluded:

"I do not alter the identity of the patient, I just choose how the patient will be represented in the data"

4.2 Temporal-Alignment and Timestamp-Decisions

Participants were also able to recognize timestamp reconciliation as a primary and repetitive part of their vascular trial work. According to CDMs, information provided by various systems, such as electronic health records, imaging systems, and laboratory systems, as well as vendor databases, had inconsistent or incomplete time information quite frequently. The solution of these contradictions was defined as a normal duty and not a unique one. One CDM explained:

"Timely schedules are not easily available. The different systems record drug administration, imaging, and adverse events, occasionally even in different time zones"

Respondents talked about time stamp inspection to identify the chronology of clinical events, especially when considering adverse events relative to interventions. Indicatively, CDMs stated that there was a comparison between the documented time of administering heparin and the occurrence of bleeding or thrombosis. In case of discrepancy, they launched data queries or referred to source documents in order to have a coherent timeline.

Another participant noted:

"When the event appears to have occurred prior to the drug but clinically it does not make sense, then we must investigate"

CDMs defined the provision of audit trails, query logs, and protocol guidance as a way of eliminating these problems. There were also instances of timestamps being fixed on source verification. In still others, CDMs recorded doubts and overruled decisions to sponsors or medical monitors. The participants highlighted that after making a decision, the generated timestamps became final, regulating downstream analyses and safety reporting. Some challenges mentioned in the CDMs were associated with the vendor system that automatically created timestamps using system clocks and not clinical occurrence. Vendors of ECG and imaging-core analysts were reported to be common causes of timing discrepancies. One respondent explained:

"The machine records the date when the file is uploaded rather than a date when the scan occurred. That disparity is important, and somebody must repair it."

Respondents accepted that decisions based on the time made influenced the classification of events but described their actions as procedural and not interpretative. They stressed on sticking to protocol rules and the expectations of regulations in solving timing problems. In general, the idea of timestamp alignment was characterized as a mechanism of building an admissible chronological history based on discontinuous pieces of information. According to CDMs, this work was critical in promoting internal consistency among datasets. As one of the participants concluded:

The timeline should be clean, otherwise nothing other in the trial will work.

4.3 Data Reduction and Normalization

The participants characterized normalization as a fundamental process where heterogeneous clinical data were transformed into standard forms, which could be analyzed. CDMs reported the process of working with data of various locations, devices and laboratories with various units, range of reference and reporting conventions. Normalization was offered as having to be done so that comparison could be made across the subjects and across the trial sites. One CDM explained:

"We could obtain laboratory values of various countries in various units. All the things must be the same language before they analyzed"

The respondents explained that they would transform the results of the laboratory tests into standardized values, map medication dosages with the aid of standard vocabularies, and match imaging results with pre-identified categories. As an illustration, the duplex ultrasound measurements of arterial stenosis were frequently converted out of continuous numerical values to categorical thresholds as stipulated by protocol. Another participant stated:

"The system does not take ranges or narratives. It wants categories. Cutting down the data till it fits."

According to CDMs, boundary values were often resolved in normalization in the process of resolving ambiguous values. In cases where the measurements were near-cutoffs, CDMs respected protocol regulations or solicited site clarification. After entering these normalized values, these formed a fixed reference point in the determination of eligibility and classification of the endpoint. The process of normalization was also characterized by the participants as one which entailed data exclusion. Values which were invalidated or were inconsistent with source documentation were occasionally not included in the final dataset. One CDM noted:

"Unless we can check it, we can not possess it. Although it may be clinically relevant"

CDMs did present that the normalization decisions were recorded using audit trails and query systems. They however admitted that normalized datasets did not capture as much variability found in the raw clinical records. Some participants acknowledged that such a decrease was an inherent characteristic of trial data management. Throughout interviews, normalization was also defined as a trade-off between standardization and completeness of data. The unified theme that CDMs gave when asked about their work was that they made sure data was adhered to protocol and regulation standards, even when this meant simplifying complicated clinical data. As one respondent concluded:

"The goal is consistency. In the absence of it, the trial can not proceed"

DISCUSSION

This paper aimed to review the mediating role of Clinical Data Managers (CDMs) in modern vascular clinical trials with patient identity by regular data-handling activities. The results indicate that CDMs are not just technical custodians of data quality, but indeed actors of mediation, who determine how participants become visible, comparable, and analyzable in the infrastructures of trials. The analysis of identity mediation practices, timestamp alignment, and normalization practices provides an empirical insight into a role that has been more of a procedural or compliance-oriented conceptualization.

5.1 Identity Mediation as Operational practice.

The results indicate that the mediation of identities is not a phenomenon that is abstract and intermittent but is a functional reality that integrates into the everyday practices of CDM. According to Chapter 4.1, CDMs make regular decisions about the representations of data that may be considered to be authoritative in the case of discrepancies among sources, including imaging cores, sites and electronic health records. It is these choices that identify the measurements, category and coded descriptions that will remain that record of a participant.

This is in line with the research on classification and data governance that maintains that structured data systems are not mere reflections of reality but also construct it. The empirical data in this paper demonstrate that mediation is an incremental process that takes place in query resolution, value selection, and coding decisions and not a single visible intervention process. Every step fixes a single version of the participant and eliminates the alternatives, creating a consistent, but inevitably partial digital identity.

Noteworthy, these practices were not characterized by the participants as discretionary or subjective in purpose. Rather they focused on compliance with protocols, validation rules and regulatory expectations. This highlights a major contribution of the research; identity mediation is not driven by the deliberate manipulation or ethical misconduct. Instead, it is brought about by the normal compliance-based activities which are required in trials to operate. Through the record of how CDMs understand that, when the data is locked, the version is the patient, the findings have been able to reveal how the identity mediation is more structural than an individual one.

5.2 Temporal Alignment as well as the Building of Clinical Sequence.

These results opine the alignment of timestamps (Section 4.2) point to the active construction of temporal coherence and not the passive recording of it. CDMs are key to aligning fragmented timelines between data systems in vascular trials that require causality and safety evaluation using accurate sequencing of interventions and events.

This research indicates that timestamps are often incompatible, because of the incompatibility of system clocks, data input

procedures, and vendor platforms. These inconsistencies are solved by CDMs by using investigation, querying, and protocol-based decision-making. These temporal decisions, once completed, determine the interpretation of adverse events as they apply to treatments, which in turn has a direct effect on the safety reporting and outcome analyses.

In terms of governance, this result contradicts the beliefs that time is a neutral or objective feature of clinical information. As an alternative, time is brought out as a negotiated phenomenon, stabilized by procedural choices. Although CDMs presented their work as the solution of technical problems, the implications are substantive: the temporal hierarchy created in the data management process turns into the basis of regulatory and scientific conclusions downstream. This supports the claim that the concept of data integrity cannot be only an issue of accuracy but also an issue of alignment. In the absence of temporal coherence, the clinical meaning would be lost. CDMs thus play the role of temporal intermediaries that make trials tell events in a form that meets the analytical and regulatory demands.

5.3 The Limits of Standardization, Reduction, and Normalization.

The normalization practices, which are discussed in Section 4.3, also indicate how clinical complexity is converted into standardized forms of analytic representations. The results indicate that CDMs routinely transform heterogeneous data (that is, data, which are the product of different locations, devices, and laboratories) into homogenous units, categories, and thresholds. This process has the benefit of having comparability, but also, it diminishes granularity.

The results of the study are consistent with the previous studies of data harmonization in multicenter trial that have identified the conflict between standardization and local specificity. In this paper, normalization was defined by CDAAM as inevitable, with the significant point that even in cases where clinical reality is continuous or ambiguous, trial systems are found to demand categorical inputs. Borderline values, subtle storylines and variation according to context are commonly reconciled into fixed categories that are maintained during analysis.

Most importantly, the participants admitted that the process of normalization implies exclusion as well. Unverifiable, reconcilable, and verifiable data are eliminated off the analytical data, even when they are considered clinically important. This brings out the epistemic implications of normalization: that which cannot be normalized cannot be counted. This paper also builds upon some of the existing literature by basing these issues on empirical descriptions of CDMs themselves. Instead of discussing normalization as an entirely technical requirement, the results demonstrate how it actively influences the process of retention and loss of particular features of patient experience. Although standardization is necessary to ensure validity of trials, it, therefore, acts as a filtering mechanism that delineates the clinical visibility.

5.4 Re-identification risk and Data Governance Implications.

Though the de-identification practices are expected to ensure the privacy of the participants, it is implied in the findings of this study (in the forebearing of Section 4.4) that CDMs are not unaware of the risks that remain in highly granular clinical data. All these measures of finer physiological data combined with time stamps and coded identifiers, may result in a profile that is hard to anonymize fully, especially on large-scale vascular trials.

This supports the issues of pseudonymization limits identified in the literature, particularly in imaging and waveform data. CDMs have gained a pivotal role in the balance between this tension: it is their role to ensure the privacy protection and maintain the utility of the data. Their choice on data retention, aggregation and documentation as such are ethical thus when framed on procedural compliance. The research adds to the discourse of governance by pointing out that the risk of privacy is not addressed at the policy level only, but in the daily operational decisions. The CDMs are gatekeepers who strike a balance between competing needs of confidentiality, scientific validity and regulatory transparency.

5.5 The Algorithmic Bias and the Standardized Patient.

Results also overlap with the problem of algorithmic bias (saw the anticipation of Section 4.5) especially in the reuse of standardized datasets to model, reuse the results of secondary analysis and automated decision-making. When the normalized data is used as an input in the algorithm systems, the decisions related to reduction made in the data management process may spread biases that were contained in the reference standards and thresholds. This is not a study that presupposes that the bias is purposely added by CDMs. Instead, it demonstrates that bias may arise indirectly in the form of applying general criteria to different groups of people. In case of deriving the physiological norms based on the majority populations, their use in heterogeneous cohorts in trials can be prejudiced to the disadvantaged groups. Through the recording of the practice of the standards by the CDMs, the study highlights the significance of reflexivity and transparency in the governance of data. Algorithms do not make data any more inclusive than the data structures on which they are built, and CDMs are a key influence on the structure of data.

5.6 Contributions and Implications

The paper has three main contributions. First, it empirically shows that CDMs are identity mediators who operate based on the routine compliance-based intervention and not extraordinary intervention. Second, it demonstrates how the features of temporal alignment and normalization are mechanisms of identity formation, as they stabilize the sequence and make it less complex. Third, it places the work of CDM in the wider ethical and governance discussions around privacy, prejudice, and data reuse.

In the case of clinical trial practice, the results indicate that more attention should be paid to the role of CDMs as interpretive actors whose choices can determine the results of scientific activities. Ethical reflection, transparency and sensitivity to representational implications as well as technical competencies should therefore be included in training programs and governance

structures. To investigate future studies, this study provides some possibilities to consider the impact of identities mediated by CDM to downstream analytics, regulatory decision-making, and patient trust. Since some trials are more and more data-intensive and algorithmically controlled, it is crucial to learn about the human labor implicated in data infrastructures.

5.1 Implications for Clinical Trials and Future Research

Due to the evolving nature of the role of CDMs in vascular trials, some implications of governance are emerging. The combination with AI-based data abstraction will set CDMs in supervisory roles where they should assess and rectify machine-generated interpretations of patient identity and clinical relevance is not compromised. The regulatory agencies like the EU Clinical Trials Regulation and the FDA Real-World Evidence Program are also piling up the pressure on transparency in terms of data transformation and its impact on identity representation. Trial governance design models start to focus on strict data lineage that mandates CDMs to illustrate how the information of each participant flows out of the raw source entries to analytical derivation destinations. Continuous training of Clinical Data Managers on specifics of data standards in various modalities, including duplex ultrasound measurements, and stent registry codes, should be integrated into vascular and endovascular clinical trials. The study recommends patient-centered governance movements are broadening the rights of the participants, providing more and more visibility of how their information is coded, cleaned, or categorized. Such changes indicate that future CDMs to be better trained and educated in ethical informatics and regulatory interpretation and communicated of patient-rights through their role as custodians of human identity within the digital environments that constitute vascular trial governance.

CONCLUSION

This study advances the current understanding by highlighting CDMs as vascular clinical trials participants who mediate identity, not as data custodians. The implications of these processes to trial governance are far reaching because AI and algorithmic systems are influencing biomedical evidence. CDMs stand at the crossroad between the precision of technical accuracy and the duty of ethics and they make decisions to decide who retains and hides the elements of patient identity. The demand to have an ethical data oversight increases with an increase in clinical trials which are complex and data-intensive. The paper suggests enhancing the training on CDM research in data ethics, regulatory interpretation, and inclusive design. The new governance models should focus on transparency, accountability, and patient agency and make the practices of data reflect the human diversity and dignity of the ever more digital of vascular research infrastructures.

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