Evaluating Clinical-Care Metadata Share and its FAIRification using the REA Ontology*

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Abstract

The FAIRification of data facilitates a fast-paced, global, FAIR metadata availability across domains for the sustainable growth of public/private organizations. Likewise, in healthcare, the clinical labs aim to achieve FAIR (biosample) metadata by keeping patient-specific infectious disease records. However, the responsible evaluation of the FAIRification process of Dutch clinical lab metadata is lacking at the local and global levels. From a responsible data science perspective, we normatively (in-principle) and empirically (in-practice) evaluate the Dutch clinical lab metadata share against FACT principles. The normative evaluation involved content analysis of FAIR concerning peer-reviewed publications and official websites. The empirical evaluation comprised a documentation review of standardized (public/confidential) documents regarding the metadata share of Dutch clinical labs. The evaluations assisted us in formulating two REA models based on REA ontology. The first REA model depicts the clinical lab metadata production run at a local/national level. The second REA model specifies the work (flow) breakdown structure of global FAIRification for FHIR Netherland using linkage relationship against FACT principles. In-field (IT and REA ontology) experts further evaluated the REA models for functional and structural veracity. Furthermore, our evaluations verified the presence of an underlying privacy-utility tradeoff in FAIRification of clinical lab metadata where data utility is prioritized over data protection.

Keywords

FAIRification, REA ontology, FACT principles, Dutch clinical-care, Responsible Data Science, Data protection, Data Utility

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1. Introduction

The recent intensified FAIRification efforts stem from including global FAIR data repositories, as an ultimate goal, by pan-European and national public authorities [1, 2, 3]. FAIRification is the process of making metadata FAIR, i.e., Findable, Accessible, Interoperable, and Reusable [4, 5, 3]. A similar FAIR data drive seeks an all-rounded, concerted technological, organizational, and strategic effort in the healthcare domain [6]. In this wake, GDPR (recital 53) obligates the member states for harmonized conditions to ensure sustainable national/central and cross-border healthcare services and systems [7]. Furthermore, for optimal data utility, GDPR (recital 5) ordains uninterrupted personal data share amongst public and private actors (i.e., both natural persons and organizations) [8]. The measures mentioned above are an extension of the GDPR objective of achieving free movement of personal data within the EU [9] and align with the FAIRification process [1, 2]. Therefore, an ethical evaluation of the FAIRification process of Dutch healthcare metadata share is required from a responsible data science (RDS) perspective [10, 11]. In this wake, an evaluation against FACT principles (of RDS) aims for fair, accurate, confidential, and transparent data handling from healthcare providers' viewpoint [11] and seek both: data utility and data protection [12]. Thus, the FACT principles seem applicable to the healthcare domain in effectively dealing with the dilemma of Privacy Utility Tradeoff (PUT), where the precision of data analytics (i.e., data utility) is as crucial as the privacy-preservation of data subjects (i.e., data protection) [13, 14, 15, 16].

***Contribution**; Using Value Modeling and the REA Ontology: Why Value Modeling?* During the last three decades, the pan-European and local regulations [17, 18, 19] gradually standardized the care services (events), the performing agents, and (metadata) resource requirements. Standardized metadata trace of patients' value care relies upon the uninterrupted (data-utility prone) care-metadata share amongst Dutch healthcare givers [15]. Data utility is the precision of (meta) data analytics, whereas data protection aims at privacy preservation of data subjects [13]. The former is an integral part of the FAIRification process [6], whereas FACT principles of RDS encompass both [11, 10]. *Why the REA Ontology?* Previously, we conceptualized the Dutch care metadata share landscape from a patient's perspective using REA ontology to highlight: the vital economic agents, their prime interactions, and collective economic value gain or loss [15, 14]. Here, the REA ontology identified the underlying financial factors and signified: who, how, and what leads to the FAIRification of Dutch clinical lab metadata at a local production run level to the global work (flow) breakdown structure level of FHIR Netherlands against FACT principles of RDS [10, 11]. The **objectives** of the research work are twofold. The first is to evaluate the (dual-level) FAIRification of Dutch clinical lab metadata against FACT principles of RDS. Secondly, to specify the findings by formulating the REA (Resource, Event, Agent) models and evaluating their functional and structural authenticity using expert opinion. To attain the objectives, we followed the approach mentioned under the data analytical approach in Section 3. The effectiveness of the selected approach relied upon following three factors. Firstly, upon the successful mapping of FACT principles on labs' (dual-level) metadata share (see FACT-mapping determinants in Section 4). Secondly, upon the simplified specification of (otherwise) complex, Dutch healthcare metadata share landscape using REA ontology. Thirdly, upon the structural and functional evaluation of REA models using expert opinion.

2. Related Work

Clinical FAIR data was reportedly first required for the timely treatment of rare diseases (5 out of 10,000) [20]. Later FAIRfication became a challenge across (research) domains to collectively overcome the hurdles [21] to reap countless socio-economic benefits [22, 4]. FACT principles were first highlighted as a concerted effort by Dutch scientists across Dutch universities for responsible data science [11, 10]. The interlink between FAIR and FACT principles was first reported in the field of crystallography [12]. Since 2018, with the implementation of GDPR [9, 7, 8], academia and industry have shown a bent toward the FAIRification of metadata across domains. For example, the Dutch healthcare enterprises [23, 24], governments bodies [25, 2], research and funding organizations [26] officially set the FAIRification process as a business goal. Data (pipeline) provenance amongst healthcare providers is maintained to attain data utility. For example, locally, the hub and spoke model [27, 28] and globally, the FAIRification of care metadata [2, 23] help assure data precision and transparency. On the other hand, data protection is achievable with fair and confidential data handling [29, 30] secured by: design, policy, and patients' informed consent [16]. The terms 'fair and confidential' have multifaceted social connotations and seek multi-dimensional means for their implications. Fair literally means 'equal treatment,' but the term has ethical implications in the healthcare domain and seeks just, benevolent and non-maleficent measures at each step of patient's value care and implies service-dominant logic [31, 32]. Confidentiality entails doing research while keeping the secrets of data subjects. Confidentiality partially covers privacy-preservation [33] and is partly ensured with technical and organizational measures for data protection [34]. Privacy seeks protection of an individual's autonomy and direct/indirect control over personal information share [35]. Both Fair and Confidential data predominantly depend upon privacy preservation, and patients' well-informed consent [36].

3. Data Analytical Approach

The Dutch clinical lab metadata share process is normatively (should-be state/ policy specification) and empirically (as-is state/operationalization) evaluated against FACT principles of RDS at local and global levels see Fig. 1. Normative evaluation includes a content analysis using peer-reviewed publications and official websites of the FAIRification process by mapping FACT principles. The empirical evaluation comprised the documentation review of standardized public/confidential documents for labs' metadata FAIRification using FACT mapping determinants. The FACT mapping [11] determinants highlighted the metadata share bend either towards data utility or data protection. Based on our evaluations, we formulated two REA models [37]. The First REA model identified the production run of patients' EHR (Electronic Health Record) by highlighting key economic agents, their increment, and decrement events using conversion duality for the clinical metadata as an economic resource. The second REA model identified FHIR, FAIR Healthcare Information Repository, Netherlands work breakdown structure vis-a-vis FACT (fair, accurate, confidential, transparent) principles. The REA models were further verified by (in-field) IT and REA ontology experts concerning the functionality and structural underpinnings of the REA models. For clarity see Fig. 1.

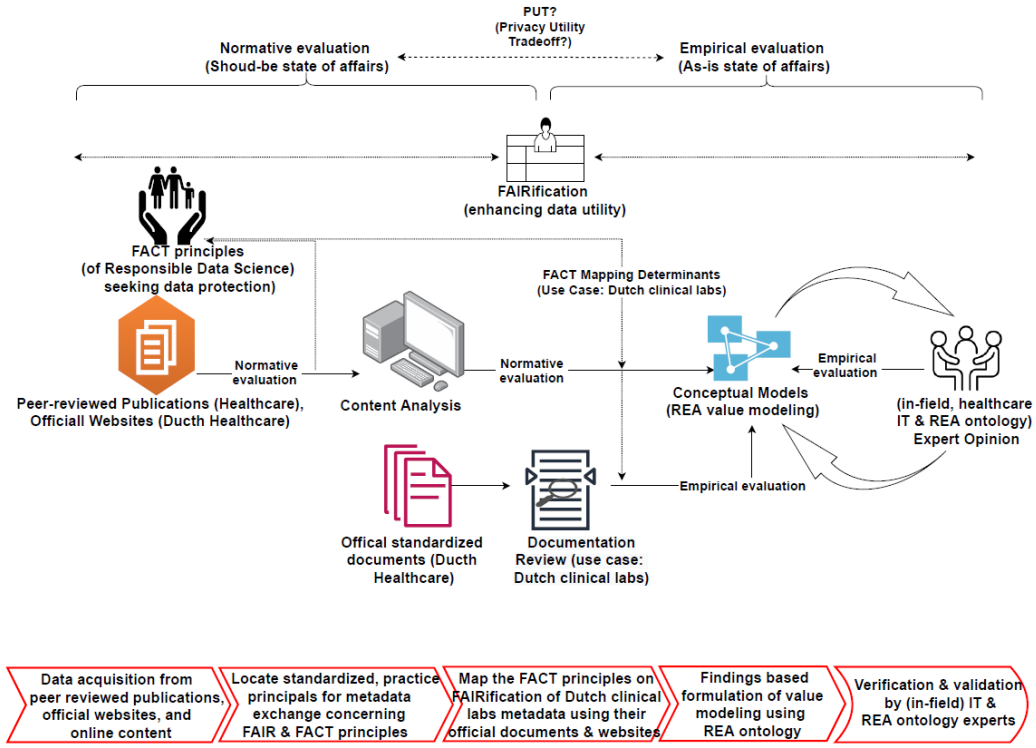

Figure 1: Data Analytical Approach.

4. REA Ontologies and Conceptual Verification using Clinical Labs as a Use Case

The below given REA models follow the foundational fundamentals by [37].

4.1. REA Model for Clinical Lab (Meta) Data Share at the Local/National Level

This REA model (see Fig. 2) exhibits the lab metadata production run [37]. Here, economic agents are a mixture of people and machines in locally sharing lab metadata as an economic resource. The applicant, i.e., the patient or the concerned healthcare giver (GP, a specialist from the hospital, or another lab), initiates the process with a (bio) sample request message as per standardized communication protocol as an increment. Then, the lab undergoes decrement events with the patient's sample intake. The sampler collects the patient's (bio) sample with a separate (unique identifier) UID. The lab transports the sample tubes to the lab analyzer/source. The analyzer with a UID is (mostly) an automatically functioning machine that conducts the 24/7 tests based on the tubes' barcodes and authorizes sample results with a UID in the lab information system. The analyzer utilizes rule-based ML algorithms. Afterward, the executor does metadata formation of lab results, allows re-identification (i.e., versioning), and attaches

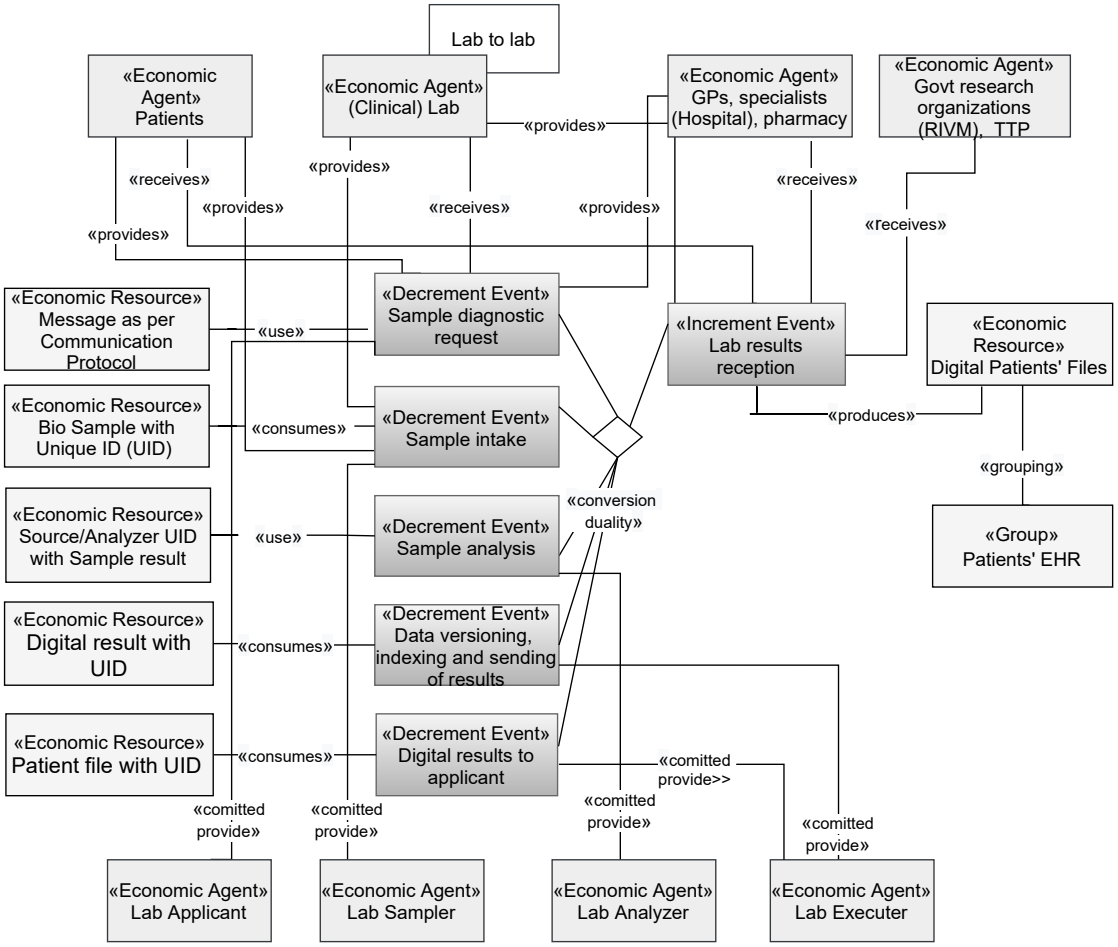

Figure 2: REA Model for the Clinical Lab (Meta) Data Production Run at a Local/National Level

results to the patient's file (i.e., indexing), respectively. The lab executer is also (mostly) an automatically functioning machine that sends a digital patient file with the lab results to the applicant's Electronic Health Record, EHR (i.e., a group [38]). The relationship "produces" can be further modeled as an REA conversion process, and we omitted the details of this process for simplicity.

FACT mapping determinants allowed mapping of FACT principles on Dutch clinical lab metadata share environment. We located the following determinants for each FACT indicator in FAIRification concerning public/confidential documents, official websites, and peer-reviewed scientific publications: for fairness: patient's right over explicit Informed Consent, data erasure/editing, data purpose, storage, and time limitations via authorities. For accuracy: provenance maintaining measures for data pipeline such as UIDs usage for precise data entry. For confidentiality: patients' sensitive information-share protection by utilizing technical, organizational, and data-oriented means. For transparency: measures to ensure re-identification of accurately published data. In FACT principles, accuracy and transparency ensure the data

utility (precision of data analytics). At the same time, fairness and confidentiality ascertain patients' data protection concerning privacy (i.e., patient's autonomous decision making concerning personal information-share) preservation. FACT principles allowed us to identify the FAIRification bend towards either data utility or data protection.

Discussion and Evaluation: The below-given insights convey the crux of clinical labs' (dual-level) metadata share evaluation. The insights highlight the areas where the FAIRification process is compared against FACT principles of RDS and show a bend towards data utility at the expense of data protection.

Insight 1, Clinical labs' data collection and metadata formulation prepare for later FAIRification: Locally, the FAIRification by design, policy, and training, corresponds with the global level go build, go change and go train [2] measures that are in place to attain FAIRification as a business goal [6, 39, 1, 26]. *FAIRifcation by design* includes standardized IS architecture, (metadata concerning) semantic models, syntax for language consistency using global UIDs for re-identification, and technical interoperability assistance by ForeCare [40]. *FAIRification by policy* ascertains [41, 42**?**] an uninterrupted, transparent exchange of care metadata across stakeholders via local/global standardizing, licensing, and oversight organizations[43]. Moreover, clinical labs share completely unmasked data with the country-wide (public) care data repository ([25]) for infectious diseases, renal diseases, antibiotic treatments, and scans. Additionally, via a national cyber-lab, the lab tests are shared with pharmacies in real-time [44, 45]. *FAIRification by training* facilitates healthcare providers' with FAIRification trainings [46, 26, 47, 48, 49] as per set (global) standards[42**?**].

Insight 2, Fully automated clinical labs, with automated IS and equipment, ensure transparent, accurate metadata but raise ethical concerns [50]. Specifically, the (presumed) machine-based decision-making algorithms for the labs' (executer) functionality in a fully automatic Lab Information System is ethically concerning [51]. *Insight 3, Partial fairness and confidentiality lead to privacy-lapse*: The technical data security measures and access governance controls are fully in place [52]. Still, privacy lapse is evident as patients' autonomous decision-making regarding personal information-share, their right to erasure/editing, knowledge for long/short term storage, and time are disregarded in an opt-out IC intake. Therefore, an explicit, well Informed Consent (IC) is less fully-practiced nationally[53, 17, 42].

4.2. REA Model for Workflow Breakdown Structure of FHIR Netherlands and FACT Mapping Derterminants

This REA model (see Fig. 3) is not an extension of the first REA model. Instead, separately emphasizes the FAIRification workflow [54, 2] of FHIR (Fast Healthcare Interoperability Resources) Netherlands [24] vis-à -vis FACT (fair, accuracy, confidentiality, transparency) principles [11]. The FACT principles ensure responsible data science, whereas the FHIR NL comprises the FAIRification procedural steps for better data utility. *FAIRification value chain* comprises data reuse, curation, validation, de- identification, semantic model implication, data linkage, licensing, versioning, data indexing, publishing, and metadata formation [54] and starts from reusable stored clinical care data for research/clinical purposes. For clarity and concision, the FAIRIfication steps [54] vis-a-vis FACT mapping determinants are condensed into 2-3 steps in the top three boxes using linkage types [37]. In the top three right boxes, the 'quantity

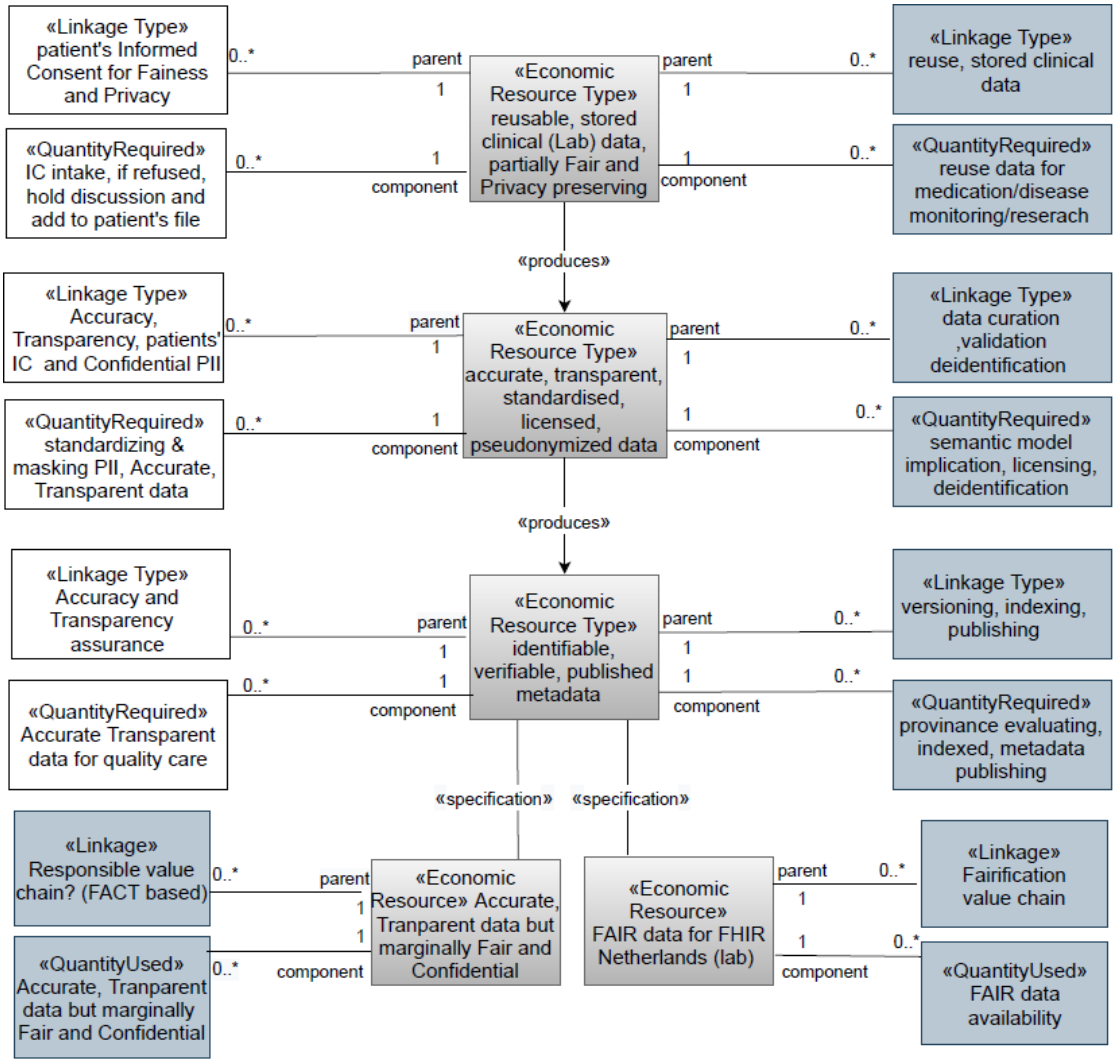

Figure 3: REA Model for Work Breakdown Structure: FHIR Netherlands vis-a-vis FACT principles.

required' are the steps required for FHIR Netherlands [41, 43, 42, 24, 55]. The dark color of these boxes emphasizes their (active) operationalization in practice. Contrarily, the left top three boxes are light-colored because the FACT principles are (officially) ordained but partially applied by downplaying fair and confidential data requirements. Finally, the top 3 (grey-colored) middleboxes specify the operationalized/practiced economic resource types that ultimately produce the economic resource of FAIR data for FHIR NL in the bottom-most (middle) boxes. Similarly, in the bottom left box, the 'quantity used' is of FACT metadata which is accurate and transparent but marginally fair and confidential.

Discussion and Evaluation: *Insight 4, Marginal fairness and confidentiality*: The gradual compromise on fair and confidential data is perceivable across the left boxes under quantity required Fig. 3 for FACT principles. Because, in addition to an implicit, marginal IC intake,

patients' de-identification is substituted with pseudonymization that allows later unmasking personal information with a key. Moreover, globally, the standardized licensing, oversight and regulatory authorities for FAIR data do the data publishing, data validating, and data versioning that further reduces data protection [49]. *Insight 5, grey areas concerning data-ownership of giant healthcare enterprises*: If labs are located within a Dutch hospital's premises, the metadata ownership rights rest unclear. The data transfer agreements with hospitals and GPs, ambiguously bridge the gap. Some out-patient Dutch clinical labs [56] are not FHIR NL members. Still, as almost all Dutch hospitals are members of FHIR NL, the former are PRESUMABLY sharing labs' clinical data via the hospital's EHR. *Insight 6, Deliberative decision-making and alignment of normative pledges and their operationalization*: There is a dire need to bridge the strategic gap between the EU policymakers, lawmakers, over-sight bodies, and the healthcare providers to align the operationalization of clinical care metadata share with the official public/confidential documents' specifications. This is only possible with the inclusion of domain-specific industry personnel into the policymaking, law-making, and oversight authorities as advisors.

5. Conclusion

We performed the evaluation of the Dutch clinical labs' (dual-level) metadata share against FACT principles of RDS. Based on the findings, we formulated two REA models that simplified the otherwise complex Dutch care metadata share landscape. The (local) production run level evaluation exhibited that the labs' metadata formulation, processing, and storing take place as per legal standards [57, 58, 59, 52] in preparation for the global FAIRification process. The FACT mapping determinants identified that the provenance of the data pipeline using UIDs ascertains the precision of data analytics (i.e., data utility) and transparency concerning patients' value care. However, labs' metadata as an economic resource is partially fair/just because of the lack of patients' explicit Informed Consent's intake by labs. Patients' confidentiality is also partially ensured because the clinical labs share unmasked data with a country-wide (public) data repository for infectious and renal diseases, antibiotic treatments, and scans. Additionally, fully automatically interacting clinical labs with automated equipment and ISs raise ethical concerns (regarding patients' confidentiality and fairness). The first REA model specified the economic agents interacting via events to perform the conversion duality of patients' metadata as an economic resource. The FACT mapping determinants demonstrate the bend towards data utility over data protection. The second REA model, specifying the work (flow) breakdown structure of FHIR NL vis-a-vis FACT mapping determinants, identifies the linkage relationship for the quantity required for each resource type (i.e., functional step). In addition, the (linkage) quantity used for the FAIR metadata in the bottom-most boxes specifies that the patients' (actual) metadata share contradicts the policy specifications in official public/confidential documents. The contradiction occurs because, with each workflow step, the FAIR data is kept: accurate and transparent but marginally fair and confidential to prioritize data utility. The research work specified and evaluated the presence of Privacy Utility Tradeoff (PUT) in the Dutch clinical labs' (dual-level) metadata share as an extension of our ongoing research [13, 14, 15, 16]. In future work, based on a more detailed local production run model, we aim to produce a mimic dataset for PUT concerning process evaluation, including possible solutions.

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