

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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100 Barangaroo Avenue
Sydney, New South Wales 2000
Australia

PCT

NOTIFICATION OF TRANSMITTAL OF
INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Rule 71.1)

Date of mailing (*day/month/year*)
14 July 2025

Applicant's or agent's file reference
229261PCT

IMPORTANT NOTIFICATION

International application No.
PCT/AU2024/050332

International filing date (*day/month/year*)
5 April 2024

Priority date (*day/month/year*)
5 April 2023

Applicant
EVIDENTLI PTY LTD

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.
- REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the *PCT Applicant's Guide*.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed invention is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 229261PCT		FOR FURTHER ACTION See Form PCT/IPEA/416																	
International application No. PCT/AU2024/050332		International filing date (<i>day/month/year</i>) 5 April 2024	Priority date (<i>day/month/year</i>) 5 April 2023																
International Patent Classification (IPC) or national classification and IPC G16B 50/20 (2019.01) G06Q 10/101 (2023.01)																			
Applicant EVIDENTLI PTY LTD																			
1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 6 sheets, including this cover sheet. 3. This report is also accompanied by ANNEXES, comprising: a. ☒ a total of 22 sheets, as follows: ☒ sheets of the description, claims and/or drawings which have been amended and/or sheets containing rectifications authorized by this Authority, unless those sheets were superseded or cancelled, and any accompanying letters (see Rules 46.5, 66.8, 70.16, 91.2, and Section 607 of the Administrative Instructions). ☐ sheets containing rectifications not taken into account by this Authority because they were not available at the time when this Authority began to draw up this report, and any accompanying letters (Rules 66.4bis, 70.2(e), 70.16 and 91.2). ☐ Superseded sheets and any accompanying letters, where this Authority either considers that the superseding sheets contain an amendment that goes beyond the disclosure in the international application as filed, or the superseding sheets were not accompanied by a letter indicating the basis for the amendments in the application filed, as indicated in item 4 of Box No. I and the Supplemental Box (see Rule 70.16(b)). b. ☐ a separate electronic file containing a sequence listing (<i>sent to the International Bureau only</i>).																			
4. This report contains indications relating to the following items: <table><tr><td>☒ Box No. I</td><td>Basis of the report</td></tr><tr><td>☐ Box No. II</td><td>Priority</td></tr><tr><td>☐ Box No. III</td><td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td></tr><tr><td>☐ Box No. IV</td><td>Lack of unity of invention</td></tr><tr><td>☒ Box No. V</td><td>Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement</td></tr><tr><td>☐ Box No. VI</td><td>Certain documents cited</td></tr><tr><td>☐ Box No. VII</td><td>Certain defects in the international application</td></tr><tr><td>☒ Box No. VIII</td><td>Certain observations on the international application</td></tr></table>				☒ Box No. I	Basis of the report	☐ Box No. II	Priority	☐ Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	☐ Box No. IV	Lack of unity of invention	☒ Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement	☐ Box No. VI	Certain documents cited	☐ Box No. VII	Certain defects in the international application	☒ Box No. VIII	Certain observations on the international application
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Date of submission of the demand 4 February 2025		Date of completion of this report 14 July 2025																	
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaaustralia.gov.au		Authorised officer David Everitt AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. +61 2 6210 8486																	

Box No. I

Basis of the report

1. With regard to the **language**, this report has been established on the basis of:
- ☒ The international application in the language in which it was filed:
- ☐ A translation of the international application into , which is the language of a translation furnished for the purposes of :
- ☐ international search (under Rules 12.3(a) and 23.1 (b)).
- ☐ publication of the international application (under Rule 12.4(a)).
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a) and (b)).
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished, or
- ☒ the description: pages **1, 4-36** , as originally filed/furnished
pages **2-3a** , received by this Authority on **10 March 2025** with the letter of **10 March 2025**
- ☒ the claims: Nos. , as originally filed/furnished
Nos. , as amended (together with any statement) under Article 19,
Nos. **1-23** , received by this Authority on **10 March 2025** with the letter of **10 March 2025**
- ☒ the drawings: pages **1/12 - 12/12** , as originally filed/furnished
pages , received by this Authority on with the letter of
- ☐ a sequence listing - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (specify):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since either they are considered to go beyond the disclosure as filed, or they were not accompanied by a letter indicating the basis for the amendments in the application as filed, as indicated in the Supplemental Box (Rules 70.2(c) and (c-bis)):
- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (specify):
5. ☐ This report has been established:
- ☐ taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.1(d-bis) and 70.2(e)).
- ☐ without taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rules 66.4bis and 70.2(e)).
6. With regard to top-up searches (Rules 66.1ter and 70.2(f)):
- ☐ A top-up search was carried out by this Authority on (date).
- ☐ Additional relevant documents have been discovered during the top-up search.
- ☒ No top-up search was carried out by this Authority because it would serve no useful purpose.
7. ☐ Supplementary international search report(s) from Authority(ies)
has/have been received and taken into account in establishing this report (Rule 45bis.8(b) and (c)).

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY		International Application No. PCT/AU2024/050332									
Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement										
1. Statement <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%; vertical-align: top;">Novelty (N)</td> <td style="width: 40%; vertical-align: top;"> Claims 1-23 Claims NONE </td> <td style="width: 30%; vertical-align: top; text-align: center;"> YES NO </td> </tr> <tr> <td style="vertical-align: top;">Inventive step (IS)</td> <td style="vertical-align: top;"> Claims NONE Claims 1-23 </td> <td style="vertical-align: top; text-align: center;"> YES NO </td> </tr> <tr> <td style="vertical-align: top;">Industrial applicability (IA)</td> <td style="vertical-align: top;"> Claims 1-23 Claims NONE </td> <td style="vertical-align: top; text-align: center;"> YES NO </td> </tr> </table>			Novelty (N)	Claims 1-23 Claims NONE	YES NO	Inventive step (IS)	Claims NONE Claims 1-23	YES NO	Industrial applicability (IA)	Claims 1-23 Claims NONE	YES NO
Novelty (N)	Claims 1-23 Claims NONE	YES NO									
Inventive step (IS)	Claims NONE Claims 1-23	YES NO									
Industrial applicability (IA)	Claims 1-23 Claims NONE	YES NO									
2. CITATIONS AND EXPLANATIONS: <u>CITATIONS</u> D1: DE MOOR, G. et al. "Using electronic health records for clinical research: The case of the EHR4CR project", Journal of Biomedical Informatics, Volume 53, 2015, Pages 162-173. https://doi.org/10.1016/j.jbi.2014.10.006 D2: GANZINGER, M. et al. "Federated electronic data capture (fEDC): Architecture and prototype", Journal of Biomedical Informatics, Vol 138 (7 January 2023), https://doi.org/10.1016/j.jbi.2023.104280 D3: HUSER, V. et al. "Standardizing data exchange for clinical research protocols and case report forms: An assessment of the suitability of the Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM)", Journal of Biomedical Informatics, Vol. 57 (2015) pp 88–99. https://doi.org/10.1016/j.jbi.2015.06.023 D4: KLANN, J.G., et al. "Data interchange using i2b2", Journal of the American Medical Informatics Association, Vol. 23, Issue 5, September 2016, pp 909–915. https://doi.org/10.1093/jamia/ocv188 D5: CLAERHOUT, B. et al. "Federated electronic health records research technology to support clinical trial protocol optimization: Evidence from EHR4CR and the InSite platform", Journal of Biomedical Informatics, Vol. 90 (2019) 103090, https://doi.org/10.1016/j.jbi.2018.12.004 D6: KROES, J.A. et al. "Blueprint for harmonising unstandardised disease registries to allow federated data analysis: prepare for the future", ERJ Open Res 2022; 8: 00168 (2022). https://doi.org/10.1183/23120541.00168-2022 D7: ONG, T.C. et al. "Dynamic-ETL: a hybrid approach for health data extraction, transformation and loading", BMC Medical Informatics and Decision Making (2017) 17:134. https://doi.org/10.1186/s12911-017-0532-3 <u>NOVELTY (N)</u> Claims 1-23 are novel and therefore comply with PCT Article 33(2) since none of the prior art documents published before the priority date individually disclose all of the features of any one of these claims. <u>INVENTIVE STEP (IS)</u> Claims 1-23 do not involve an inventive step and therefore do not comply with PCT Article 33(3). <i>Addressing independent claims 1 and 12:</i> Regarding claim 1, D1 discloses a computer-implemented federated studies system (D1: EHR4CR - Electronic Health Records for Clinical Research) comprising: a predefined common data model associated with a study (D1: Section 4.2.1 - CDISC/HL7 BRIDG, OMOP common data model)											
Form PCT/IPEA/409 (Box V) (revised January 2019)											

a set of sites of origin, each site of origin being associated with: (i) a set of input devices for acquiring study data from subjects, and (ii) a study data device

(D1: Fig 1 and Section 3.3 - data sources)

wherein each study data device includes: a native database for storing study data associated with the respective site of origin and derived from said set of input devices

(D1: Fig 1 and Section 4.2.3)

a data model translator for translating stored study data to a format corresponding to said common data model

(D1: Section 4.2.3 - use of an ETL strategy)

a common model database for storing, in said common data model, individual participant values derived from said study data

(D1: Fig 1 and Section 4.2.3 - the EHR4CR DM)

a study compute module for determining site aggregate values from said individual participant values

(D1: Section 4.2.4 - aggregated numbers and results)

and an aggregate database for storing said site aggregate values

(D1: Fig 1)

and a site of analysis coupled to each site of origin via a communications network

(D1: Fig 1: EHR4CR central platform; Fig 9; Section 4.2.5)

wherein said site of analysis is associated with a study analysis device that includes: an analysis compute module for processing, in accordance with a predefined analysis profile, site aggregate values received from said sites of origin

(D1: Section 4.2.5 and Figs 5, 7, 9)

and a reporting module for generating study reports based on said processed site aggregate values

(D1: Section 3.3; Fig 6)

D1 does not disclose a central repository for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets associated with each site of origin. However a such data translation elements are well-known, and there is no invention in storing them in a central repository.

D1 also does not disclose an Identifier Issuing Service configured to interface between each site of origin and said central repository to ensure elements within data sets having the same semantic meaning have a common unique identifier. However this additional feature of an Identifier Issuing Service for managing extensions simply defines the functions of such a service. Identifier Issuing Services for a wide variety of applications are well-known in the art, and the claimed functions do not address any extension-related features which are specific to a federated study. Therefore, at the claimed level of detail, the use of an Identifier Issuing Service does not contribute to providing an inventive step.

Claim 12 recites a method with features similar to those of the system of claim 1, excluding the feature of ensuring that elements within data sets having the same semantic meaning have a common unique identifier, and therefore lacks an inventive step for similar reasons s claim 1. While claim 12 recites the functions of the Identifier Issuing Service in greater detail than in claim 1, these functions merely use standard features such as forwarding requests and issuing unique identifiers which do not contribute to providing an inventive step.

Addressing dependent claims 2-11 and 13-23:

Regarding **claim 2**, the additional feature wherein said predefined analysis profile is stored in a repository of analyses associated with said site of analysis is considered to be a matter of non-inventive design choice regarding the storage of the analysis profile.

Regarding **claims 3 and 17**, the additional feature wherein said common data model is selected from specified models is disclosed in D1 (D1: Section 4.2.1 - OMOP COM).

Regarding **claims 4 and 18**, the additional feature wherein said study reports are presented in specified ways is disclosed in D1 (D1: Section 4.2.5 and Fig 8- dashboard; Fig 6 - an electronic document).

Regarding **claims 5 and 19**, the additional feature wherein the input devices are adapted to digitally capture data for use in a federated study is disclosed in D1 (D1: abstract and Section 1 - data is captured from EHR systems).

Regarding **claim 6 and 20**, the additional feature wherein the input devices are selected from specified systems is disclosed in D1 (D1: abstract and Section 1 - electronic health records systems).

Regarding **claims 7 and 15**, the additional feature wherein the predefined analysis profile defines a set of computer-implementable instructions for analysing a set of data is implicit in D1 as the analysis is computer-implemented.

Regarding **claims 8 and 21**, the additional feature wherein each study data device is a computer-implemented study data device coupled to said respective set of input devices; wherein said study analysis device is a computer-implemented study analysis device; and further wherein each study data device and said study analysis device are coupled utilising at least one communications link is disclosed in D1 (D1: Fig 1).

Regarding **claims 9, 10 and 22**, the additional features wherein the study data device is implemented in a cloud-computing environment or where the study analysis device is device is implemented in a cloud-computing environment or a computing device is considered to be a matter of non-inventive design choice since the use of computing devices and cloud computing environments were well-known for performing data processing well before the priority date of this application.

Regarding **claims 11 and 23**, the additional feature wherein each Site of Origin includes a translation client configured to transmit a request for a new extension upon detection of a need for a new extension to at least one of the common data model or the set of analysis instructions is considered to be obvious when need for a new extension is detected.

Regarding **claim 13**, the additional feature wherein the method comprises the further step, at each said Site of Origin, of: generating a report based on said processed site aggregate values and individual participant values is considered to be a non-inventive choice regarding where and how the reporting takes place.

Regarding **claim 14**, the additional feature wherein said analysis instructions include a predefined analysis profile is disclosed in D1 (D1: Fig 5).

Regarding **claim 16**, the additional feature wherein said set of computer-implementable instructions include specified instructions is considered to be obvious, as each of the specified instructions define straightforward and obvious computer instructions.

Documents D2-D6 when considered in the light of common general knowledge also render one or more claims as obvious to a person skilled in the art - see references in the International Search Report.

INDUSTRIAL APPLICABILITY (IA)

The invention defined in the claims is considered to meet the requirements of Industrial Applicability under Article 33(4) of the PCT because it can be made by, or used in, industry.

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

A search was performed because a meaningful search was considered possible following the PCT search and examination guidelines, however the material claimed is considered to be excluded subject matter under the rules of the PCT, being a scheme for implementing a federated workflow.

The scope of **claim 12** is unclear as it recites "*on receipt of a request for a new extension*", without indicating how or when such a request might be initiated.

10 March 2025

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Our Ref: 229261PCT

International Patent Application No. PCT/AU2024/050332
Evidentli Pty Ltd
Computer-implemented system and method for secure federated studies

RESPONSE TO WRITTEN OPINION

The Applicant acknowledges receipt of the International Search Report and Written Opinion of the ISA dated 21 June 2024 in respect of the above-noted matter.

Article 34 amendments

The Applicant requests that the specification be amended under PCT Article 34 as follows:

1. Replace original pages 2 and 3 with new pages 2, 3, and 3a.
2. Replace original claim pages 37 to 42 with new claim pages 37 to 42.

The amendments are summarised as follows:

- Independent Claim 1 is amended to define the invention more clearly by reciting the features of:
(1) a central repository for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets associated with each site of origin; and
(2) an Identifier Issuing Service configured to interface between each site of origin and said central repository to ensure elements within data sets having the same semantic meaning have a common unique identifier. Support for the amendment may be found at original claim 11.
- Corresponding amendments have been made to independent claim 12, with support for the amendment being found at original claim 23.
- Claim 12 is amended to improve clarity by reciting “said defined set of analysis instructions”.

The Applicant submits that no new material has been added.



Submissions in response to Written Opinion

Novelty

The Examiner contends that **claims 1, 3-8, 12, 14-15, and 17-21** lack novelty in light of:

- **D1: "Using electronic health records for clinical research: The case of the EHR4CR project", Journal of Biomedical Informatics, Volume 53, 2015, Pages 162-173.**

The Applicant respectfully disagrees.

The present application is directed to ameliorating one or more problems that arise from harmonizing real-world data across multiple sites and using such harmonized data in observational research, including dialect formation and loss of precision.

The amended form of claim 1 recites the following features, which have been elevated from original claim 11 that was found to be novel in the Written Opinion:

*a central repository for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets associated with each site of origin; and
an Identifier Issuing Service configured to interface between each site of origin and said central repository to ensure elements within data sets having the same semantic meaning have a common unique identifier.*

As discussed in the present application at [0134] – [0136], dialects are often formed when attempting to harmonize data sets obtained from multiple different sites. Dialects may be formed from interpretation and/or omission. As set out at [0136], interpretation “occurs when the instructions of how to model data to a standard are ambiguous or unclear in some other way, leaving room for data transformers at different sites and/or at different times to interpret those instructions differently”. Omission “occurs when the standard developers did not foresee a use case when the standard was published, and before some of the data needed to be represented by the data model are known”, as described at [0137].

The combination of a central repository and an Identifier Issuing Service unifies data translations across the plurality of States of Origin provides a technical, reusable solution to both the dialect formation and loss of precision problems described above.

The cited document D1 describes an application designed to be used in clinical trials as an alternative to electronic data capture (EDC) applications. In particular, D1 relates to using electronic health records for clinical research (EHR4CR) and describes a data model translator corresponding to the translator 114 of the present application. In contrast, the present application is agnostic to the method or tool used for translating data models.

D1 discusses scenarios in which the same translator is used at every site separately. D1 describes the use of such translators in the basic environments that are described in the present application as suffering from two main problems:

1. susceptibility to the formation of dialects (or fragmentation of the data model), which leads to the different sites, even if using the same common data model and even the same data model translator, being **compliant** to the same common data model, but being **incompatible** with each other (as described in paragraphs 134-183 of the present application); and
2. loss of precision of the statistical analysis that normally affects federated studies (as described in paragraphs [0038]-[0133] of the present application).

Not only does D1 not address these problems, D1 does not even acknowledge the existence of such problems.

As D1 does not disclose the features of the amended form of independent claims 1 and 12, the Applicant submits that amended claims 1 and 12, and the claims that depend therefrom, are novel.

Inventive Step

The Examiner contends that **claims 1 to 23** lack an inventive step in light of D1 when considered in light of the common general knowledge. The Examiner further contends that documents D2-D6:

- **D2: “Federated electronic data capture (fEDC): Architecture and prototype”, Journal of Biomedical Informatics, Vol 138 (7 January 2023), <https://doi.org/10.1016/j.jbi.2023.104280>**
- **D3: “Standardizing data exchange for clinical research protocols and case report forms: An assessment of the suitability of the Clinical Data Interchange Standards Consortium (CDISC) Operational Data Model (ODM)”, Journal of Biomedical Informatics, Vol. 57 (2015) pp 88–99. <https://doi.org/10.1016/j.jbi.2015.06.023>**
- **D4: “Data interchange using i2b2”, Journal of the American Medical Informatics Association, Vol. 23, Issue 5, September 2016, pp 909–915. <https://doi.org/10.1093/jamia/ocv188>**
- **D5: “Federated electronic health records research technology to support clinical trial protocol optimization: Evidence from EHR4CR and the InSite platform”, Journal of Biomedical Informatics, Vol. 90 (2019) 103090, <https://doi.org/10.1016/j.jbi.2018.12.004>**
- **D6: “Blueprint for harmonising unstandardised disease registries to allow federated data analysis: prepare for the future”, ERJ Open Res 2022; 8: 00168 (2022). <https://doi.org/10.1183/23120541.00168-2022>**

render obvious one or more of the claims when considered in light of the common general knowledge, without providing any specifics.

The Examiner asserts, in considering original claim 11, that the feature of an Identifier Issuing Service for managing extensions simply defines the functions of such a service. The Applicant respectfully disagrees and submits that the Examiner has failed to consider the combination of features of original claim 11 and their working inter-relationship.

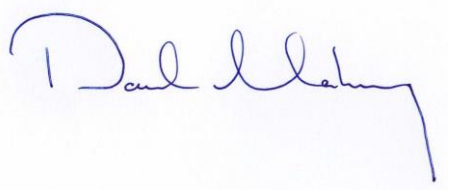
Relevantly, the newly amended form of claim 1 recites the features of the **central repository** for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets and an **Identifier Issuing Service** that interfaces between each site of origin and the central repository to ensure that elements within data sets having the same semantic meaning have a common unique identifier. It is the interaction among the central repository, the sites of origin, and the Identifier Issuing Authority that ensures that dialects are not formed across different sites of origin, resulting in a technical platform for improved federated studies.

None of the cited documents is directed to the problems discussed above in relation to the formation of dialects or loss of precision in federated studies. Moreover, none of the cited documents even mentions these problems, indicating that none of the cited documents discloses the solution of the present application.

The Applicant submits that a person of ordinary skill in the art would not be led, directly as a matter of course, from the teachings of any of the cited documents, when considered alone or in combination with the common general knowledge, to arrive at the solution of the presently claimed invention, as none of the cited documents even considers the problems of dialect formation in federated studies and thus does not provide any teaching as to how to resolve such dialect formation issues.

The Applicant respectfully requests reconsideration of the claims and the issuance of a clear IPRP.

Yours faithfully



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Encl.

- 2 -

materials used can differ and thus produce unexplained inaccuracies in the study results. Further, non-technical restrictions may affect the collation of data, such as jurisdictional legal requirements regarding privacy and data transmission.

[0007] Thus, a need exists to provide an improved system for conducting federated studies.

Summary

[0008] The present disclosure relates to a computer-implemented system and associated methods to conduct federated studies.

[0009] A first aspect of the present disclosure provides a computer-implemented federated studies system comprising:

- a predefined common data model associated with a study;
- a set of sites of origin, each site of origin being associated with a set of input devices for acquiring study data from subjects and a study data device, wherein each study data device includes:
 - a native database for storing study data associated with the respective site of origin and derived from said set of input devices;
 - a data model translator for translating stored study data to a format corresponding to said common data model;
 - a common model database for storing, in said common data model, individual participant values derived from said study data;
 - a study compute module for determining site aggregate values from said individual participant values; and
 - an aggregate database for storing said site aggregate values; and
- a site of analysis coupled to each site of origin via a communications network, wherein said site of analysis is associated with a study analysis device that includes:
 - an analysis compute module for processing, in accordance with a predefined analysis profile, site aggregate values received from said sites of origin; and
 - a reporting module for generating study reports based on said processed site aggregate values;
- a central repository for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets associated with each site of origin; and
- an Identifier Issuing Service configured to interface between each site of origin and said central repository to ensure elements within data sets having the same semantic meaning have a common unique identifier.

- 3 -

[0010] A second aspect of the present disclosure provides a method of conducting a federated study across a plurality of sites of origin and using a site of analysis, the method comprising the steps of:

- defining a common data model for the study;

- defining a set of analysis instructions for the study;

- at each site of origin:

- acquiring, utilising least one input device, study data from a set of subjects;

- translating said study data to generate individual participant values stored in said common data model;

- processing said individual participant values to generate a set of site aggregate values;

- transmitting said site aggregate values to said site of analysis; and

- processing study aggregate values received from said Site of Analysis in accordance with said defined set of analysis instructions; and

- at said site of analysis:

- processing site aggregate values received from at least one of said sites of origin in accordance with said defined set of analysis instructions; and

- generating a report based on said processed site aggregate values;

- wherein the method unifies data translations across said plurality of Sites of Origin

by:

- storing in a central repository a set of data translation elements for managing extensions and mappings within the federated study;

- on receipt of a request for a new extension, an Identifier Issuing Service communicating with said central repository to determine whether the requested extension exists;

- when the requested extension exists, the Identifier Issuing Service retrieving the requested extension from the central repository and forwarding the requested extension to the requesting translation client, and

- when the requested extension does not exist, the Identifier Issuing Service:

- issuing a new unique identifier for the requested extension,

- forwarding the new identifier for the requested extension to the requesting translation client, and

- forwarding the new identifier for the requested extension to the central repository for storage.

[0011] According to another aspect, the present disclosure provides an apparatus for implementing any one of the aforementioned methods.

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[0012] According to another aspect, the present disclosure provides a computer program product including a computer readable medium having recorded thereon a computer program that when executed on a processor of a computer implements any one of the methods described above.

[0013] Other aspects of the present disclosure are also provided.

Brief Description of the Drawings

[0014] One or more embodiments of the present disclosure will now be described by way of specific example(s) with reference to the accompanying drawings, in which:

[0015] Fig. 1 is a schematic block diagram representation of a computer-implemented federated study system in accordance with an embodiment of the present disclosure;

[0016] Fig. 2 is a schematic block diagram representation of a Site of Analysis in accordance with an embodiment of the present disclosure;

[0017] Fig. 3 is a schematic block diagram representation of a Site of Origin in accordance with an embodiment of the present disclosure;

[0018] Fig. 4 is a schematic block diagram representation of a federated studies system on which one or more embodiments of the present disclosure may be practised;

[0019] Fig. 5 is a schematic block diagram representation of a system that includes a general purpose computer on which one or more embodiments of the present disclosure may be practised;

We claim:

1. A computer-implemented federated studies system comprising:
 - a predefined common data model associated with a study;
 - a set of sites of origin, each site of origin being associated with: (i) a set of input devices for acquiring study data from subjects, and (ii) a study data device, wherein each study data device includes:
 - a native database for storing study data associated with the respective site of origin and derived from said set of input devices;
 - a data model translator for translating stored study data to a format corresponding to said common data model;
 - a common model database for storing, in said common data model, individual participant values derived from said study data;
 - a study compute module for determining site aggregate values from said individual participant values; and
 - an aggregate database for storing said site aggregate values; and
 - a site of analysis coupled to each site of origin via a communications network, wherein said site of analysis is associated with a study analysis device that includes:
 - an analysis compute module for processing, in accordance with a predefined analysis profile, site aggregate values received from said sites of origin; and
 - a reporting module for generating study reports based on said processed site aggregate values;
 - a central repository for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets associated with each site of origin; and
 - an Identifier Issuing Service configured to interface between each site of origin and said central repository to ensure elements within data sets having the same semantic meaning have a common unique identifier.
2. The system according to claim 1, wherein said predefined analysis profile is stored in a repository of analyses associated with said site of analysis.
3. The system according to either one of claim 1 or claim 2, wherein said common data model is selected from the group consisting of: Observational Medical Outcomes Partnership Common Data Model (OMOP CDM), Oracle Health Foundations, National Patient-Centered Clinical Research Network (PCORNet), Sentinel, and Informatics for Integrating Biology & the Bedside (I2B2).

4. The system according to any one of claims 1 to 3, wherein said study reports are presented as at least one of: a user interface dashboard for display on a computing device, a printed report, an electronic document, an email, and a webpage.
5. The system according to any one of claims 1 to 4, wherein the input devices are adapted to digitally capture data for use in a federated study.
6. The system according to claim 5, wherein the input devices are selected from the group consisting of: electronic health records systems, patient administration systems, medication ordering systems, survey systems, wearable devices, laboratory sensors, imaging machines, electronic thermometers, weather data systems, and computer-implemented data entry devices.
7. The system according to any one of claims 1 to 6, wherein the predefined analysis profile defines a set of computer-implementable instructions for analysing a set of data.
8. The system according to any one of claims 1 to 7,
wherein each study data device is a computer-implemented study data device coupled to said respective set of input devices;
wherein said study analysis device is a computer-implemented study analysis device;
and
further wherein each study data device and said study analysis device are coupled utilising at least one communications link.
9. The system according to claim 8, wherein at least one of said study data devices is implemented in a cloud-computing environment.
10. The system according to any one of claims 1 to 9, wherein the federated studies system is implemented using at least one of a computing device or a distributed cloud-based architecture.
11. The system according to any one of claims 1 to 10:
wherein each said data model translator includes a translation client configured to communicate with the Identifier Issuing Service when the respective data model translator determines a need for an extension,

wherein said Identifier Issuing Service, on receipt of a request for an extension from a translation client:

- communicates with said central repository to determine whether the requested extension exists;

- when the requested extension exists, the Identifier Issuing Service retrieves the requested extension from the central repository and forwards the requested extension to the requesting translation client, and

- when the requested extension does not exist, the Identifier Issuing Service:

 - issues a new unique identifier for the requested extension,

 - forwards the new identifier for the requested extension to the requesting translation client, and

 - forwards the new identifier for the requested extension to the central repository for storage.

12. A method of conducting a federated study across a plurality of Sites of Origin and using a Site of Analysis, the method comprising the steps of:

- defining a common data model for the study;

- defining a set of analysis instructions for the study;

- at each Site of Origin:

 - acquiring, utilising least one input device, study data from a set of subjects;

 - translating said study data to generate individual participant values stored in said common data model;

 - processing said individual participant values to generate a set of site aggregate values;

 - transmitting said site aggregate values to said site of analysis; and

 - processing study aggregate values received from said Site of Analysis in accordance with said defined set of analysis instructions; and

- at said Site of Analysis:

 - processing site aggregate values received from at least one of said Sites of Origin in accordance with said defined set of analysis instructions; and

 - generating a study report based on said processed site aggregate values;

wherein the method unifies data translations across said plurality of Sites of Origin by:

- storing in a central repository a set of data translation elements for managing extensions and mappings within the federated study;

on receipt of a request for a new extension, an Identifier Issuing Service communicating with said central repository to determine whether the requested extension exists;

when the requested extension exists, the Identifier Issuing Service retrieving the requested extension from the central repository and forwarding the requested extension to the requesting translation client, and

when the requested extension does not exist, the Identifier Issuing Service:

issuing a new unique identifier for the requested extension,

forwarding the new identifier for the requested extension to the requesting translation client, and

forwarding the new identifier for the requested extension to the central repository for storage.

13. The method according to claim 12, wherein the method comprises the further step, at each said Site of Origin, of:

generating a report based on said processed site aggregate values and individual participant values.

14. The method according to either one of claim 12 or claim 13, wherein said analysis instructions include a predefined analysis profile.

15. The method according to claim 14, wherein the predefined analysis profile defines a set of computer-implementable instructions for analysing a set of data.

16. The method according to claim 15, wherein said set of computer-implementable instructions include:

definitions of each of the site aggregate values and study aggregate values,
arithmetic and data manipulation operations used to calculate said each of said site aggregate values and said study aggregate values,
instructions for transmission of site aggregate values from sites of origin to the site of analysis,
instructions for receiving site aggregate values from the sites of origin by the site of analysis,
instructions for transmission of study aggregate values from the site of analysis to the sites of origin,

instructions for receiving study aggregate values from the site of analysis by the sites of origin,

instructions for the order of said data manipulation, transmission and reception instructions, and

composition of a report for each one of said Sites of Origin and said Site of Analysis.

17. The method according to any one of claims 12 to 16, wherein said common data model is selected from the group consisting of: Observational Medical Outcomes Partnership Common Data Model (OMOP CDM), Oracle Health Foundations, National Patient-Centered Clinical Research Network (PCORNet), Sentinel, and Informatics for Integrating Biology & the Bedside (I2B2).

18. The method according to any one of claims 12 to 17, wherein said study report is presented as at least one of: a user interface dashboard for display on a computing device, a printed report, an electronic document, an email, and a webpage.

19. The method according to any one of claims 12 to 18, wherein the input devices are adapted to digitally capture data for use in a federated study.

20. The method according to claim 19, wherein the input devices are selected from the group consisting of: electronic health records systems, patient administration systems, medication ordering systems, survey systems, wearable devices, laboratory sensors, imaging machines, electronic thermometers, weather data systems, and computer-implemented data entry devices.

21. The method according to any one of claims 12 to 20,
wherein each study data device is a computer-implemented study data device coupled to said respective at least input device;

wherein said study analysis device is a computer-implemented study analysis device;
and

further wherein each study data device and said study analysis device are coupled utilising at least one communications link.

22. The method according to claim 21, wherein at least one of said study data devices is implemented in a cloud-computing environment and said study analysis device is implemented in a cloud-computing environment.

23. The method according to any one of claims 12 to 22, wherein each Site of Origin includes a translation client configured to transmit a request for a new extension upon detection of a need for a new extension to at least one of the common data model or the set of analysis instructions.

materials used can differ and thus produce unexplained inaccuracies in the study results. Further, non-technical restrictions may affect the collation of data, such as jurisdictional legal requirements regarding privacy and data transmission.

[0007] Thus, a need exists to provide an improved system for conducting federated studies.

Summary

[0008] The present disclosure relates to a computer-implemented system and associated methods to conduct federated studies.

[0009] A first aspect of the present disclosure provides a computer-implemented federated studies system comprising:

- a predefined common data model associated with a study;
- a set of sites of origin, each site of origin being associated with a set of input devices for acquiring study data from subjects and a study data device, wherein each study data device includes:
 - a native database for storing study data associated with the respective site of origin and derived from said set of input devices;
 - a data model translator for translating stored study data to a format corresponding to said common data model;
 - a common model database for storing, in said common data model, individual participant values derived from said study data;
 - a study compute module for determining site aggregate values from said individual participant values; and
 - an aggregate database for storing said site aggregate values; and
- a site of analysis coupled to each site of origin via a communications network, wherein said site of analysis is associated with a study analysis device that includes:
 - an analysis compute module for processing, in accordance with a predefined analysis profile, site aggregate values received from said sites of origin; and
 - a reporting module for generating study reports based on said processed site aggregate values;
- a central repository for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets associated with each site of origin; and
- an Identifier Issuing Service configured to interface between each site of origin and said central repository to ensure elements within data sets having the same semantic meaning have a common unique identifier.

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[0010] A second aspect of the present disclosure provides a method of conducting a federated study across a plurality of sites of origin and using a site of analysis, the method comprising the steps of:

defining a common data model for the study;

defining a set of analysis instructions for the study;

at each site of origin:

acquiring, utilising least one input device, study data from a set of subjects;

translating said study data to generate individual participant values stored in said common data model;

processing said individual participant values to generate a set of site aggregate values;

transmitting said site aggregate values to said site of analysis; and

processing study aggregate values received from said Site of Analysis in accordance with said ~~translated~~ defined set of analysis instructions; and

at said site of analysis:

~~translating said analysis instructions;~~

processing site aggregate values received from at least one of said sites of origin in accordance with said ~~translated~~ defined set of analysis instructions; and

generating a report based on said processed site aggregate values;

wherein the method unifies data translations across said plurality of Sites of Origin

by:

storing in a central repository a set of data translation elements for managing extensions and mappings within the federated study;

on receipt of a request for a new extension, an Identifier Issuing Service communicating with said central repository to determine whether the requested extension exists;

when the requested extension exists, the Identifier Issuing Service retrieving the requested extension from the central repository and forwarding the requested extension to the requesting translation client, and

when the requested extension does not exist, the Identifier Issuing Service:

issuing a new unique identifier for the requested extension,

forwarding the new identifier for the requested extension to the requesting translation client, and

forwarding the new identifier for the requested extension to the central repository for storage.

[0011] According to another aspect, the present disclosure provides an apparatus for implementing any one of the aforementioned methods.

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[0012] According to another aspect, the present disclosure provides a computer program product including a computer readable medium having recorded thereon a computer program that when executed on a processor of a computer implements any one of the methods described above.

[0013] Other aspects of the present disclosure are also provided.

Brief Description of the Drawings

[0014] One or more embodiments of the present disclosure will now be described by way of specific example(s) with reference to the accompanying drawings, in which:

[0015] Fig. 1 is a schematic block diagram representation of a computer-implemented federated study system in accordance with an embodiment of the present disclosure;

[0016] Fig. 2 is a schematic block diagram representation of a Site of Analysis in accordance with an embodiment of the present disclosure;

[0017] Fig. 3 is a schematic block diagram representation of a Site of Origin in accordance with an embodiment of the present disclosure;

[0018] Fig. 4 is a schematic block diagram representation of a federated studies system on which one or more embodiments of the present disclosure may be practised;

[0019] Fig. 5 is a schematic block diagram representation of a system that includes a general purpose computer on which one or more embodiments of the present disclosure may be practised;

We claim:

1. A computer-implemented federated studies system comprising:
 - a predefined common data model associated with a study;
 - a set of sites of origin, each site of origin being associated with: (i) a set of input devices for acquiring study data from subjects, and (ii) a study data device, wherein each study data device includes:
 - a native database for storing study data associated with the respective site of origin and derived from said set of input devices;
 - a data model translator for translating stored study data to a format corresponding to said common data model;
 - a common model database for storing, in said common data model, individual participant values derived from said study data;
 - a study compute module for determining site aggregate values from said individual participant values; and
 - an aggregate database for storing said site aggregate values; and
 - a site of analysis coupled to each site of origin via a communications network, wherein said site of analysis is associated with a study analysis device that includes:
 - an analysis compute module for processing, in accordance with a predefined analysis profile, site aggregate values received from said sites of origin; and
 - a reporting module for generating study reports based on said processed site aggregate values;
 - a central repository for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets associated with each site of origin; and
 - an Identifier Issuing Service configured to interface between each site of origin and said central repository to ensure elements within data sets having the same semantic meaning have a common unique identifier.
2. The system according to claim 1, wherein said predefined analysis profile is stored in a repository of analyses associated with said site of analysis.
3. The system according to either one of claim 1 or claim 2, wherein said common data model is selected from the group consisting of: Observational Medical Outcomes Partnership Common Data Model (OMOP CDM), Oracle Health Foundations, National Patient-Centered Clinical Research Network (PCORNet), Sentinel, and Informatics for Integrating Biology & the Bedside (I2B2).

4. The system according to any one of claims 1 to 3, wherein said study reports are presented as at least one of: a user interface dashboard for display on a computing device, a printed report, an electronic document, an email, and a webpage.
5. The system according to any one of claims 1 to 4, wherein the input devices are adapted to digitally capture data for use in a federated study.
6. The system according to claim 5, wherein the input devices are selected from the group consisting of: electronic health records systems, patient administration systems, medication ordering systems, survey systems, wearable devices, laboratory sensors, imaging machines, electronic thermometers, weather data systems, and computer-implemented data entry devices.
7. The system according to any one of claims 1 to 6, wherein the predefined analysis profile defines a set of computer-implementable instructions for analysing a set of data.
8. The system according to any one of claims 1 to 7,
wherein each study data device is a computer-implemented study data device coupled to said respective set of input devices;
wherein said study analysis device is a computer-implemented study analysis device;
and
further wherein each study data device and said study analysis device are coupled utilising at least one communications link.
9. The system according to claim 8, wherein at least one of said study data devices is implemented in a cloud-computing environment.
10. The system according to ~~either one of claim 8 or claim 9, wherein said study analysis device is implemented in a cloud-computing environment~~any one of claims 1 to 9, wherein the federated studies system is implemented using at least one of a computing device or a distributed cloud-based architecture.
11. The system according to any one of claims 1 to 10,~~further comprising:~~

~~a central repository for storing and retrieving a set of data translation elements for managing extensions and mappings within study data sets associated with each site of origin; and~~

~~an Identifier Issuing Service configured to interface between each site of origin and said central repository to ensure elements within data sets having the same semantic meaning have a common unique identifier;~~

wherein each said data model translator includes a translation client configured to communicate with the Identifier Issuing Service when the respective data model translator determines a need for an extension,

wherein said Identifier Issuing Service, on receipt of a request for an extension from a translation client:

communicates with said central repository to determine whether the requested extension exists;

when the requested extension exists, the Identifier Issuing Service retrieves the requested extension from the central repository and forwards the requested extension to the requesting translation client, and

when the requested extension does not exist, the Identifier Issuing Service:

issues a new unique identifier for the requested extension,

forwards the new identifier for the requested extension to the requesting translation client, and

forwards the new identifier for the requested extension to the central repository for storage.

12. A method of conducting a federated study across a plurality of Sites of Origin and using a Site of Analysis, the method comprising the steps of:

defining a common data model for the study;

defining a set of analysis instructions for the study;

at each Site of Origin:

acquiring, utilising least one input device, study data from a set of subjects;

translating said study data to generate individual participant values stored in said common data model;

processing said individual participant values to generate a set of site aggregate values;

transmitting said site aggregate values to said site of analysis; and

processing study aggregate values received from said Site of Analysis in accordance with said ~~translated~~ defined set of analysis instructions; and

at said Site of Analysis:

~~translating said analysis instructions;~~

processing site aggregate values received from at least one of said Sites of Origin in accordance with said ~~translated~~ defined set of analysis instructions; and

generating a study report based on said processed site aggregate values;

wherein the method unifying unifies data translations across said plurality of Sites of Origin by:

storing in a central repository a set of data translation elements for managing extensions and mappings within the federated study;

on receipt of a request for a new extension, an Identifier Issuing Service communicating with said central repository to determine whether the requested extension exists;

when the requested extension exists, the Identifier Issuing Service retrieving the requested extension from the central repository and forwarding the requested extension to the requesting translation client, and

when the requested extension does not exist, the Identifier Issuing Service:

issuing a new unique identifier for the requested extension,

forwarding the new identifier for the requested extension to the requesting translation client, and

forwarding the new identifier for the requested extension to the central repository for storage.

13. The method according to claim 12, wherein the method comprises the further step, at each said Site of Origin, of:

generating a report based on said processed site aggregate values and individual participant values.

14. The method according to either one of claim 12 or claim 13, wherein said analysis instructions include a predefined analysis profile.

15. The method according to claim 14, wherein the predefined analysis profile defines a set of computer-implementable instructions for analysing a set of data.

16. The method according to claim 15, wherein said set of computer-implementable instructions include:

definitions of each of the site aggregate values and study aggregate values,

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arithmetic and data manipulation operations used to calculate said each of said site aggregate values and said study aggregate values,

instructions for transmission of site aggregate values from sites of origin to the site of analysis,

instructions for receiving site aggregate values from the sites of origin by the site of analysis,

instructions for transmission of study aggregate values from the site of analysis to the sites of origin,

instructions for receiving study aggregate values from the site of analysis by the sites of origin,

instructions for the order of said data manipulation, transmission and reception instructions, and

composition of a report for each one of said Sites of Origin and said Site of Analysis.

17. The method according to any one of claims 12 to 16, wherein said common data model is selected from the group consisting of: Observational Medical Outcomes Partnership Common Data Model (OMOP CDM), Oracle Health Foundations, National Patient-Centered Clinical Research Network (PCORNet), Sentinel, and Informatics for Integrating Biology & the Bedside (I2B2).

18. The method according to any one of claims 12 to 17, wherein said study report is presented as at least one of: a user interface dashboard for display on a computing device, a printed report, an electronic document, an email, and a webpage.

19. The method according to any one of claims 12 to 18, wherein the input devices are adapted to digitally capture data for use in a federated study.

20. The method according to claim 19, wherein the input devices are selected from the group consisting of: electronic health records systems, patient administration systems, medication ordering systems, survey systems, wearable devices, laboratory sensors, imaging machines, electronic thermometers, weather data systems, and computer-implemented data entry devices.

21. The method according to any one of claims 12 to 20,
wherein each study data device is a computer-implemented study data device coupled to said respective at least input device;

wherein said study analysis device is a computer-implemented study analysis device;
and

further wherein each study data device and said study analysis device are coupled
utilising at least one communications link.

22. The method according to claim 21, wherein at least one of said study data devices is
implemented in a cloud-computing environment and said study analysis device is
implemented in a cloud-computing environment.

23. The method according to any one of claims 12 to 22, wherein each Site of Origin
includes a translation client configured to transmit a request for a new extension upon
detection of a need for a new extension to at least one of the common data model or the set
of analysis instructions, the method comprising the further steps of:

~~unifying data translations across said plurality of Sites of Origin by:~~

~~storing in a central repository a set of data translation elements for managing
extensions and mappings within the federated study;~~

~~on receipt of a request for a new extension, an Identifier Issuing Service
communicating with said central repository to determine whether the requested
extension exists;~~

~~when the requested extension exists, the Identifier Issuing Service retrieving the
requested extension from the central repository and forwarding the requested
extension to the requesting translation client, and~~

~~when the requested extension does not exist, the Identifier Issuing Service:~~

~~issuing a new unique identifier for the requested extension;~~

~~forwarding the new identifier for the requested extension to the requesting
translation client, and~~

~~forwarding the new identifier for the requested extension to the central
repository for storage.~~