Assessing the research potential of access to clinical trial data: Summary

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Introduction

Clinical trials generate systematic and vital information about the efficacy, safety and quality of medical interventions. However, there has been much discussion about the degree to which trial results and the underpinning data are currently made available to researchers outside of the team that conducted the original trial. Recent legislation and various initiatives have started to contribute to increased availability of data from clinical trials, predominantly at summary level, but also at the level of the individual trial participant. This enhanced access not only allows for more transparency in clinical research, but can also drive generation of knowledge, allowing researchers to tackle new research questions, to reduce duplication and optimise the design of trials, or to increase the efficiency of the research process by linking data from multiple trials. However, substantial barriers to accessing individual participant data (IPD) continue to exist. Overcoming these barriers offers the potential for improved access to clinical trial data and for fully exploiting existing research data to the benefit of the scientific community and, ultimately, the patient.

This report presents the findings of a study commissioned by the Wellcome Trust in April 2014. The study draws on independent research carried out by Technopolis Group, and was supported by an independent expert review group comprised of Mike Clarke (Queen's University Belfast), Trudie Lang (University of Oxford), Fiona Reddington (Cancer Research UK), Matt Sydes (Medical Research Council Clinical Trials Unit at University College London), and Catrin Tudur Smith (University of Liverpool).

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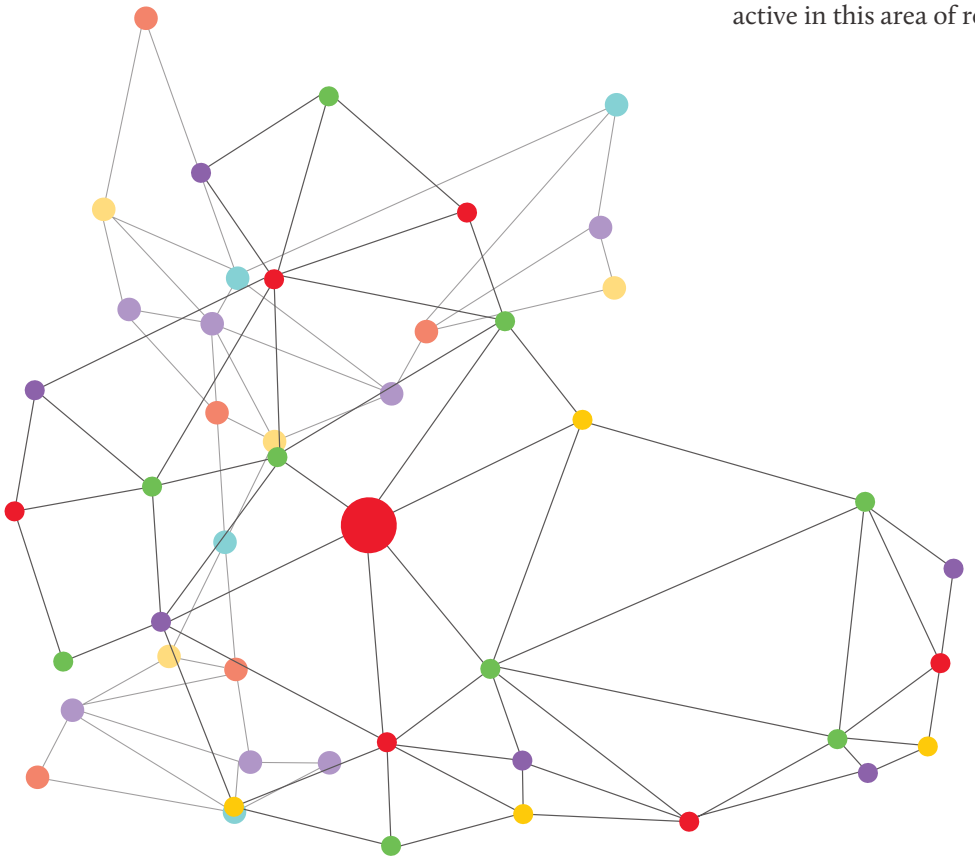
The summary and full report are available to download from **wellcome.ac.uk/clinicaldata**

Objectives

The primary aims of this study were to develop an understanding of the types of novel clinical research that may be possible using IPD from clinical trials, and to develop case studies of existing and future examples of such research and its benefits. The study also aimed at assessing the potential level of demand for a broader access model for such clinical trial data, and whether there are appreciable differences between the academic and commercial research communities in terms of needs and use of clinical trial data. The study ultimately seeks to contribute to discussions about key mechanisms and practicalities that would need to underlie a broader access model for clinical trial data.

While increased transparency is an important outcome of data sharing, the emphasis of this study was on investigating the use of clinical trial data to drive generation of new knowledge.



Methodology

The study examined the history and set-up of existing data sharing initiatives, their current research use, and impacts achieved. It also gathered views regarding the current barriers to research using IPD and the need for broader access to IPD, via a central access point or otherwise, by consulting researchers from commercial and non-commercial entities, staff of clinical trial data repositories, and individuals affiliated with clinical research such as representatives of funding organisations and patient groups. Further questions gauged the perceived level of importance of various characteristics of a future access model, in order to allow researchers from the academic, non-profit, and industrial sectors to contribute data and share research benefits, while protecting patient privacy and respecting the wishes of trial participants regarding re-use of their data.

The study utilised both quantitative and qualitative research methods including: desk research; a global online survey of clinical trial researchers and relevant stakeholders from sectors including universities and research institutes, hospitals and healthcare professionals, industry, research funders, patients groups, and regulators; a stakeholder workshop; and targeted interviews with relevant individuals active in this area of research.

Existing data sharing initiatives

We analysed the key characteristics of 18 existing IPD sharing initiatives, and found they clustered into the following five broad categories (named to reflect their main properties):

- Collaborative groups of trialists/trial sponsors
- Disease-specific data repositories
- Public-funder mandated repositories
- Commercial trial repositories and data portals
- Open data sharing by individual research groups/units.

Collaborative groups of trialists/trial sponsors were created as research collaborations, rather than initiatives to enable broad data access, with the aim of addressing a specific disease area or task. These initiatives hold data from academic and commercial trials, generally from both control and treatment arms. Database staff harmonise the data on receipt. While access by researchers from outside the collaboration is possible, data providers retain control over their datasets and can veto requests for access. We found that these types of initiatives tended to yield substantial benefits for research and patients.

Examples of this type of data sharing initiative include the Early Breast Cancer Trialists' Collaborative Group (EBCTCG), the WorldWide Antimalarial Resistance Network (WWARN), and initiatives of consortia of the Critical Path (C-Path) Institute.

Disease-specific data repositories were created with the aim of accelerating development of treatments through enhanced data access for the wider research community, and tend to be funded by disease charities. These include disease-specific data from academic and commercial trials, but generally only from the control arm of the trial, or from "failed" trials in disease areas the company providing the data is no longer active in. Database staff harmonise data, and grant access following guidelines agreed with the data providers. Some databases in this group have seen data access levels of between 50 and 200 times per year. We found that the organisations coordinating these databases were spending, or planning to spend, a lot of effort on promotion, or on further incentivising their use as many researchers were not aware of these resources.

Examples of this type of data sharing initiative include the PRO-ACT database for Amyotrophic Lateral Sclerosis (ALS), the CODR database for Alzheimer's Disease, and the database of the Sylvia Lawry Centre for Multiple Sclerosis (MS) Research.

Funder-mandated repositories were created as a platform for depositing data from publicly funded research. Such databases have been implemented by several institutes of the US National Institutes of Health (NIH) for research funded through their grant mechanisms, and are often linked to other types of data (genetic data, observational studies) and/or biospecimens. Harmonisation of data occurs at different points – some databases require the data provider to standardise data to their requirements prior to submission, others leave this to the user of the repository. This may be reflected in the observed differences in usage levels, ranging from more than 100 requests per year for datasets harmonised by the depositor, to less than 20 requests per year for repositories with unharmonised data. Several repositories indicated issues with timely deposition of data by the original researcher, and the need for monitoring compliance.

Examples of this type of data sharing initiative include the BioLINCC repository of the National Heart, Lung, and Blood Institute (NHLBI), the data repository of the National Institute for Diabetes, Digestive, and Kidney Diseases (NIDDK), and the National Database for Clinical Trials (NDCT) of the National Institute of Mental Health (NIMH).

Commercial trial repositories and data portals were created as a platform or portal to allow access to data, in the first instance from commercial clinical trials. They are fairly recent initiatives, providing (or starting to provide) access to data from industry-sponsored clinical trials. Most datasets are held on the trial sponsor's server, and access is granted by an independent review board following an agreed application process. In some cases, however, companies retain a right to deny access. Approved researchers can analyse the data within a secure environment; in exceptional cases, data transfer to the user's server may be considered. We found that researchers in general welcomed these new initiatives, but we also heard about cases when access to data via a "remote desktop" presented challenges to efficient analysis.

Examples of this type of data sharing initiative include the Clinical Study Data Request (CSDR) portal and the Yale University Open Data Access (YODA) Project.

Open access datasets have been made available for download by individual research groups or units to allow broad access to IPD without the need to contact the original researchers. While most of the data are available without any restrictions, part of the dataset may be withheld from the open access interface in order to prevent misinterpretation of the data (e.g. the randomisation code for the FREEBIRD database). This approach ensures complete accessibility to datasets. However, as datasets are currently held on many different data platforms, in distributed locations, researchers may need support to be able to find and combine these to maximise data use.

Examples of this type of data sharing initiative include the FREEBIRD and International Stroke Trial (IST) databases.

Current research practices

Over recent decades, the number of articles reporting IPD meta-analyses has risen considerably: while only 57 articles were published before 2000, an average of nearly 50 articles per year were published between 2005 and 2009.

Access to IPD provides a number of potential advantages over access to summary-level data. IPD allows researchers to analyse clinical trial data outside the original purpose of the trial, including "dividing up" datasets to identify specific subgroups of trial participants, and investigate time-sequence events, the effect of multiple factors in different combinations, and rare events.

We found examples of meta-analyses using IPD in a number of disease areas leading to an improved understanding of treatment benefits and risks, the development of prognostic models, the development of new analysis methods, and identification of inconsistencies in clinical trial data collection and assays. Enhanced access to IPD from clinical trials is expected to increase such research outcomes (e.g. in disease areas not yet investigated in this manner). In addition, secondary analyses of IPD could lead to novel insights drawing on the statistical power of the large volume of combined data, such as an understanding of causes and treatments for common conditions or symptoms, where there is significant heterogeneity across the patient population (e.g. pain and rheumatoid arthritis), or the occurrence of extremely rare events, such as adverse events in patients who were not considered at risk initially (e.g. stroke in young persons), drawing on the large scale of high-quality data available.

A survey of clinical trial researchers and relevant stakeholders, conducted as part of this study with a total of 386 respondents, indicated that respondents were predominantly involved in, or aware of, projects using IPD to address cancer (54%). This was followed by cardiovascular disease (36%), central nervous system or neuromuscular conditions (32%), mental health and behavioural conditions (23%), and digestive/endocrine, nutritional and metabolic diseases (23%). The principal research objectives of these projects were comparison of effects of different interventions (82%), and assessment of potential adverse effects of a drug or other interventions (61%). Projects made use of data on health outcomes (83%), demographics (78%), clinical laboratory test results (73%), medical history (71%), and adverse events (64%). A higher proportion of respondents from companies indicated use of adverse events data (84%) as compared to the overall survey population.

Survey respondents indicated that a variety of statistical methods and techniques had been used to analyse IPD. Most projects involved multivariate (75%) and univariate (47%) analysis, and logistic regression (51%). The use of less traditional techniques, such as data mining (22%), machine learning (9%), and genetic algorithms (6%), was also noted.

Two-thirds of survey respondents (66%) indicated that IPD analysed in projects they were involved in, or were aware of, were generated and held by the organisation where they worked. This figure was even higher for respondents from companies, rising to 80%. Only 21% had obtained the data through an established repository. Nearly half of the survey respondents indicated that they had not made any data requests in the previous year (43%). This figure was higher for respondents from industry (65%).

The majority of survey respondents, including respondents from companies, thought the ability to access IPD from clinical trials would enhance the quality of research (34%), or even influence the direction of research (36%). Only 7% thought that enhanced access would not change the research, and that all the IPD currently needed were accessible.

Current research barriers and preferred characteristics of a broader access model

The survey asked respondents to rate the impact of a range of current barriers to IPD research. Similarly, respondents rated the importance of a number of characteristics of a potential future IPD access model. Rankings of barriers and characteristics by perceived level of impact and importance are provided in Table 1 and Table 2, respectively, along with a summary of preferred characteristics of a future data sharing model in Box 1.

Survey respondents indicated that the most serious barriers to research projects involving IPD were current access to relevant existing datasets (with 66% indicating this had a "significant impact" on research projects or completely "blocked" those), and incomplete knowledge of what data exist (with 52% indicating a "significant impact" on or "blocking" research). This was followed by concerns over data not being mapped to a common standard, concerns about participant consent, and being restricted to data analysis on the data owner's or repository server (respectively, with 42%, 41%, and 40% of survey respondents indicating a "significant impact" on, or "blocking" research).

Compared to the overall population of survey respondents, respondents from industry tended to be more concerned about providing competitive advantage to others, with 43% indicating "significant impact" on or "blocking" the research project, compared to 26% of all respondents.

Table 1, Current barriers to research using individual participant data	
Barriers to current IPD research	**Score**
Access to relevant existing datasets	2.8
Incomplete knowledge of what data currently exist	2.4
Available data are not mapped to a common standard	2.3
Data can only be analysed on data owner's/repository server	2.2
Concerns about participant's consent for data sharing	2.2
Concerns about sharing research proposals due to current proposal review practices	2.0
Ownership terms of research results are not favourable to researchers	2.0
Stringent credentials required for data requestors to access data	1.9
Concerns about identification of participants in the data	1.9
Concerns about providing competitive advantage to others	1.7

Survey question: "Based on your experience, please rate on a scale from 0 to 4 the extent to which the following current barriers have an impact on researchers conducting projects involving individual participant data." n range: 312 - 370

Table 2, Preferred characteristics for access to individual participant data	
Characteristics of future IPD access model	**Score**
Researchers are provided with technical information in relation to trials/datasets within the repository	3.2
Datasets include both commercial and academic trial data	3.0
Datasets can be downloaded for analysis	2.8
Data are harmonised and presented in a single format	2.8
Datasets from all trials are accessible on a central repository	2.7
Datasets include trial data from all regions of the world	2.7
Datasets include historical data	2.5
Researchers can use any analysis software on a central data access server	2.5
Concerns about identification of participants in the data	1.9
Concerns about providing competitive advantage to others	1.7

Survey question: "Please rate on a scale from 0 to 4 the importance of the following statements relating to the characteristics of a future data repository for the type of research you/your colleagues may want to conduct." n range: 320 - 331

Box 1 Preferred characteristics of a future sharing model for individual participant data from clinical trials, based on survey responses
One central repository
Repository includes data from academic/non-commercial and commercial trials
Data are held by a trusted third party
Datasets are curated to a high standard
Access is reviewed by an independent review board
Data can be downloaded to user's server
Datasets are harmonised
Historical data are included
Data from all regions are incorporated

Referring to a potential future IPD access model, respondents saw benefits to all characteristics investigated in the survey. The majority felt that it was most important to provide researchers with technical information in relation to accessed datasets (with 77% indicating this was of "significant importance" or "essential"). Respondents also considered it "significantly important" or "essential" that a future sharing initiative include both commercial and academic trial data (70%), that datasets could be downloaded for analysis (68%), and that data were harmonised and presented in a single format (65%). Industry respondents assigned less importance to all characteristics listed in the survey, with the largest difference in the importance attributed to the ability to download data for analysis (with only 33% of industry respondents indicating this was "significantly important" or "essential", compared to 68% of the total survey population).

Survey respondents' main concern about enhanced access to IPD was "losing control" over the data (40%), which included potential issues around patient privacy, misinterpretation or deliberate misuse of data, potential lack of appropriate patient consent for secondary analysis, or fear of criticism of the original analysis. The fear that data would be exploited without any benefit for the original researcher or study sponsor was also seen as impeding researchers' willingness to deposit data (34%). A smaller number of respondents listed concerns about the cost and effort involved in preparing and uploading datasets (11%). Views on what would stop researchers from requesting access covered a range of issues. The largest number of respondents cited concerns over the quality of deposited data (34%), and a burdensome administrative approval process (20%).

Compared to the current situation, many more survey respondents were expecting to make requests for data should enhanced access became available. While 43% had not requested any data over the last year, only 14% thought they would not request any data from a database with a suitable access mechanism. Similarly, respondents from industry signalled a shift in the number of requests, with the proportion of those who requested data one or more times increasing from 35% last year to 77%.

Key considerations for a broader data access model

The views of experts consulted as part of this study were largely positive regarding enhanced access to IPD via a central access point, and the research opportunities afforded through such an initiative. However, it was evident that there were substantial concerns about the practicalities and potential risks. The benefits highlighted and concerns expressed are summarised below.

The **benefits of a central access model for IPD** were that it would:

- Increase transparency
- Save time and effort required for new analyses, by providing a single/a small number of access points to data, with legal aspects of data sharing already taken care of
- Enhance data quality and value, and uncover potential issues in data collection and interpretation
- Increase data discoverability
- Avoid duplication of research
- Draw in new research communities, by lowering the effort required for researchers external to the core clinical trial community to access data.

The **drawbacks of a central access model for IPD** were that it would:

- Disconnect the original researcher from the dataset, and hence increase the potential risk of incorrect analysis
- Represent a significant cost to data providers and repositories, with the possibility that many datasets will never be re-used
- Put researchers in resource-limited countries at a disadvantage, by placing data at the hands of experts in highly-funded research institutions without research benefit for those who collected the data.

In addition, survey respondents and interviewees highlighted the misalignment between the benefits of data sharing and rewards for the original researchers/trial sponsors. This ranges from the cost and effort of preparing datasets for sharing, the lack of recognition of the data contribution made, and a loss of control over the dataset leading to potentially increased risks, such as misuse of data, giving competitive advantage to other researchers or companies, and loss of intellectual property.

Regarding the **scope of a central IPD access model** suitable to maximise research benefits, experts consulted broadly agreed that:

- Data from academic and non-commercial trials should be provided alongside commercial trial data, as these often addressed complementary research questions. Respondents did not foresee any real barriers to combining the data.
- Access to trials from all geographic regions was desirable but not practically achievable. Data from disease areas that would especially benefit from access to global data should be prioritised, rather than trying to gather all data from the outset.
- Access to historical data was desirable, especially in research areas where long-term follow-up data exist, but not practically achievable across all disease areas given the cost implications. Data from disease areas that would especially benefit from historical data should be prioritised. Researchers conducting secondary analysis needed to be made aware of potential pitfalls when analysing these data, such as differences in data collection due to changes in medical technology.
- Other types of data should be combined with, or at least linked to, the numerical data from clinical trials. This includes data from observational studies, which provide important long-term datasets complementary to the shorter-term clinical trial data, and images, which are essential in some disease areas.

Regarding **access mechanisms for a future IPD access model**, to enable the broadest possible use of the data while keeping risks at an acceptable level, most survey respondents (61%) and interviewees felt that reviewed access to datasets held by a trusted custodian was most suitable. However, while half of survey respondents (49%) considered the open access model least suitable, a substantial proportion (25%) chose this as the most suitable model, indicating that the scientific community does not currently have a broad agreement on this point.

Concerns about data continuing to be held by the original research or trial sponsor included potential data censorship, increased difficulty in aggregating data if datasets were stored in multiple locations, and the often restrictive nature of commercial trial sponsors' data environments.

Potential **risks of enhanced access to IPD, and suggested mitigation measures** included:

- The potential for breach of patient privacy. This could be limited by removing additional data parameters from the trial dataset, and/or by limiting access to bona fide researchers vetted via a robust review process.
- Providing competitive advantage for others. For academic research groups, this could be limited by allowing sufficient time for the original researcher to exploit the data before external access is granted, or requiring the original researcher to be informed of, or potentially involved in, any subsequent projects. This risk is difficult to address in a commercial setting.
- Rogue analysis, either through lack of knowledge or malicious intent. Suggestions for how this risk could be limited included:
  - extensive data curation of deposited data, and availability of detailed technical information alongside the dataset(s)
  - limiting access to research teams with the right skills and credentials
  - requiring submission of a clearly outlined research proposal along with the request for access
  - requiring the original researcher to be informed of, and potentially involved in, any subsequent projects.

In addition, it was evident that the lack of clarity on patient consent forms concerning secondary use of data needs to be addressed, with some interviewees calling for the development of a standard question addressing this issue, to be included on all forms going forward.

Regarding **data format and the analysis environment**, survey respondents and interviewees broadly agreed that data needed to be curated to a high standard to make those valuable. Respondents also thought it important that researchers could download data to their servers, or at least use any analysis software they wanted on the remote desktop provided by the repository or data portal. Harmonisation of data across datasets held in a central database was desirable, but not realistic on a global scale. A number of views were put forward as to when data should be harmonised (at the point of data deposition or when requested) and by whom (data provider or data user), to optimise capturing the full value of the data while keeping this effort to a reasonable level. Existing databases use a range of models, which may account for different levels of data requests from the research community.

Key findings

Key findings regarding the types of novel clinical research that may be possible using IPD from clinical trials:

1. Over the last decade, the number of publications of secondary analysis using existing IPD from clinical trials has significantly increased in the scientific literature.
2. A survey carried out as part of the study showed that respondents were predominantly involved in, or aware of, research using IPD in the areas of cancer and cardiovascular disease, with the principal objectives of comparing the effects of different treatments, assessing the occurrence of adverse events by subgroup analysis, identifying new biomarkers, and aiding the design of new clinical trials.
3. Outcomes achieved include the development of disease-progression models, qualification of new biomarkers and endpoints for use in clinical trials, and dose optimisation in patient subgroups.
4. Enhanced access to IPD was expected to broaden these outcomes further across other disease areas and enable novel research to improve our understanding of the causes of, and treatments for, common conditions with significant heterogeneity across the patient population, as well as the causes of rare events.
5. The majority of survey respondents were involved in, or aware of, research using IPD held by their own organisations, or shared within the academic community. Although a range of data sharing initiatives is available, study informants indicated that these were used to a lesser degree.
6. Eighteen data sharing initiatives were examined in more detail, and found to group into the following five categories: collaborations of trialists/trial sponsors, disease-specific repositories, funder-mandated access repositories, commercial trial data portals, and open-access initiatives. Individual data holdings exhibit varying degrees of "openness", scale, and focus.

Key findings about the potential level of demand for a broader access model for IPD from academic and non-commercial trials:

7. The main barriers to research employing IPD were identified as issues related to "not knowing what data exist", i.e., discoverability, and access to data. The majority of survey respondents thought the ability to access IPD through a central data access point would enhance the quality, and even influence the direction, of their research.
8. Broader availability of data was expected to increase the number of requests for sharing of datasets, especially from industry survey respondents.
9. Most survey respondents considered it "significantly important" or "essential" that a future data access model includes both commercial and academic trial data. This view was mirrored by interviewees who felt that these data complement each other, and that it was hence important to be able combine both types for research.

Key findings about the mechanisms and practicalities that would need to underlie a broader access model for clinical trial data:

10. Survey respondents deemed reviewed access, rather than open access, the most suitable data access mechanism, and indicated that data should ideally be held by an independent data custodian, accessible via a central point, and curated to a high standard.
11. The majority of survey respondents felt that it was "significantly important" that data were harmonised and could be downloaded to the user's server. Respondents from industry assigned less importance to these factors. In interviews, the points were raised that harmonisation of the entire body of data within a large repository was not practically achievable, and it was advisable to harmonise data in research priority areas initially.

Recommendations

Based on the evidence gathered, the following set of recommendations was developed:

1. **Link current data sharing initiatives and prevent further fragmentation of data landscape**

- Promote the establishment of larger data holdings, with the clear aim of incorporating IPD from both commercial and non-commercial clinical trials.
- Initiate enhanced information exchange between existing data sharing initiatives and support linking of existing repositories and data portals.

2. **Confirm demand for IPD**

- Establish a central information website, or consider adapting current clinical trial registries, with profiles and links to existing repositories and data portals.
- Ensure that funding streams for sharing and/or secondary analysis of existing clinical trial data are available to facilitate generation of new knowledge.
- Monitor actual demand and research outcomes following promotion of available repositories and data portals.

3. **Address current barriers to IPD research in a joined-up approach**

- Establish a central repository or data portal to facilitate access to IPD from clinical trial data. Such an effort may need to take the form of a small number of regional repositories on compatible data platforms.
- Establish a global discussion forum of potential funders of IPD sharing initiatives to develop global support and a joined-up approach leading to the implementation of globally "linkable" IPD repositories and data portals.

4. **Develop a suitable repository platform**

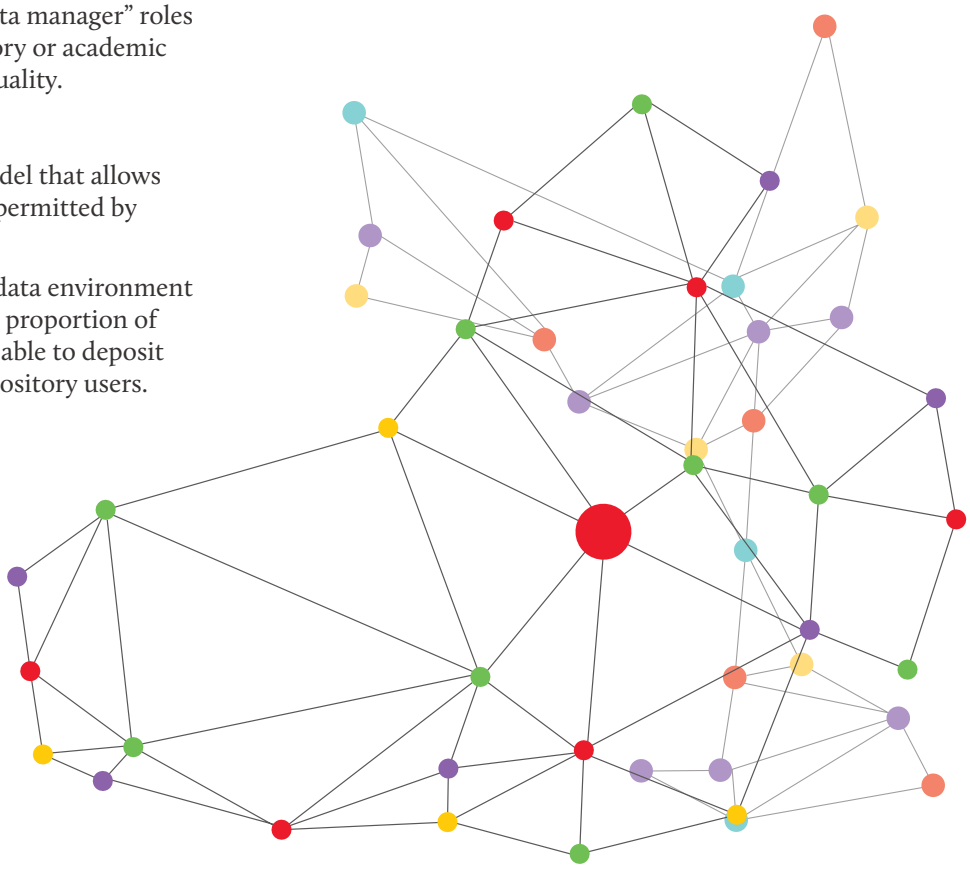
- Evaluate current data sharing platforms against desired characteristics, and for suitability for expansion, to develop and implement a data sharing platform drawing on best practice from existing repositories.
- In case different data sharing requirements prevent some data providers from joining the "new" repository or data portal from the outset, continue dialogue to allow data linkage at a future point.

5. **Scale the repository**

- Global reach: implement a pilot repository in one or a small number of regions to develop a robust, cost-efficient solution that could function as a model for future efforts in other regions.
- Historical data:
  - Adopt a case-by-case approach to incorporate historical data, i.e., only in research priority areas or as mandated by individual funders.
  - Establish clear processes for deposition of historical data in priority research areas.
- Other types of data:
  - Support information exchange with existing IPD sharing initiatives from other disciplines (e.g. public health).
  - Identify options for future linkage across databases.

6. Enable research while ensuring appropriate use of data

- Access modality:
  - Develop a repository model with reviewed access and data held by a trusted third party.
  - Carry out a detailed comparison of review parameters of existing data sharing initiatives to identify best practice and challenges, and develop an effective, streamlined process.
  - Incorporate open access options to allow data providers to make suitably de-identified data available without review, should they wish to do so, and monitor demand, actualised risks, and research outcomes to inform further efforts.
- Data format:
  - Adopt a case-by-case approach to data harmonisation, rather than aiming to harmonise all data from the outset.
  - Establish processes for harmonisation of IPD across trials in priority research areas that offer individual funders the option of carrying out these activities.
  - Adopt or develop, and test, data handling tools to facilitate data deposition.
  - Investigate staffing needs and "data manager" roles to provide support at the repository or academic institutions to assure high data quality.
- Data analysis environment:
  - Implement an IPD repository model that allows the user to download data when permitted by the data provider.
  - Investigate the need for a secure data environment for analysis, as determined by the proportion of data providers who would not be able to deposit data if it were downloaded by repository users.



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