			ensure that the design of the study meets appropriate standards and to ensure appropriate conduct and reporting). The primary sponsor is normally the main applicant for regulatory authorisation to begin the study. It may or may not be the main funder.
6.	**Secondary Sponsor(s)**	Name	Additional individuals, organisations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship. A secondary sponsor may have agreed o to take on all the responsibilities of sponsorship jointly with the primary sponsor; or o to form a group with the primary sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or o to act as the sponsor's legal representative in relation to some or all of the trial sites o to take responsibility for the accuracy of trial registration information submitted
7.	**Contact for Public Queries**	Email, telephone number, or address	Email address, telephone number, or address of the contact who will respond to general queries, including information about current recruitment status
8.	**Contact for Scientific Queries**	Email, telephone number, or address Affiliation	Email address, telephone number, or address, and affiliation of the person to contact for scientific inquiries about the trial (e.g., principal investigator, medical director for the study at the sponsor). For a multi-center study, enter the contact information for the lead Principal Investigator or overall medical director.
9.	**Public Title**		Title intended for the lay public in easily understood language.
10.	**Scientific Title**	Acronym	*The SAG did not reach agreement on this item during the Advisory Group meeting.*
11.	**Countries of Recruitment**		The countries from which participants will, are planned, or have been recruited (as last reported to the Primary Register).
12.	**Health Condition(s) or Problem(s) Studied**		Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). Enter one term per line in the field.
13.	**Intervention(s)**	Intervention name(s)	Enter the specific name of the intervention(s) and the comparator/control being studied, one at a time. Use the International Non-

		Other details (e.g., dose, duration, etc) Click to add more experimental interventions... Control Intervention name Other details of control (e.g., dose, duration, etc.) Click to add more control interventions...	Proprietary Name if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable). If the intervention consists of several separate treatments, list in one line separated by commas (e.g., "low-fat diet, exercise"). For multi-armed studies, describe the intervention(s) for each arm in separate entries. The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g., placebo, no treatment, active control). If an active control is used, be sure to enter in the name(s) of that as well, or enter "placebo" or "no treatment" as applicable for the control arm. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc)
14.	**Key Inclusion and Exclusion Criteria**	Inclusion Criteria Exclusion Criteria	Inclusion and exclusion criteria for participant selection, including age and sex.
15.	**Study Type**	Single group study? If a multiple group study, is it randomized?	A single group study is one in which all participants are given the same intervention. Trials in which participants are assigned to receiving one of two or more interventions are NOT single group studies. Crossover trials are NOT single group studies. For multiple group studies (2 or more study groups), a trial is "randomized" if participants are/were assigned to intervention groups by a method based on chance.
16.	**Date of First Enrollment**		Anticipated or actual date of enrollment of the first participant (MM/YYYY).
17.	**Target Sample Size**		Number of participants that this trial plans to or had planned to enroll as last reported to the Primary Register.
18.	**Recruitment Status**		Recruitment status of this trial, as last reported to the Primary Register. o Pending: participants are not yet being recruited or enrolled at any site o Active: participants are currently being recruited and enrolled o Temporary halt: there is a temporary halt in recruitment and enrollment o Closed: participants are no longer being recruited or enrolled

19.	**Primary Outcome(s)**	Outcome Name Timepoints Click to add more outcomes...	Outcomes are events or experiences that trial investigators measure because it is believed that they may be influenced by the intervention or exposure. The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effect of the intervention(s). Enter the names of all primary outcomes of the trial, one at a time. Be as specific as possible (e.g., "Beck depression score"rather than just "depression"). For each outcome, also provide all the timepoints at which it is to be measured. Examples: Outcome Name: all cause mortality, Timepoints: one year; or Outcome Name: Beck depression score, Timepoint: 6,12, and 18 weeks
20.	**Key Secondary Outcomes**	Outcome Name Timepoints Click to add more outcomes...	Outcomes are events or experiences that trial investigators measure because it is believed that they may be influenced by the intervention or exposure. Secondary outcomes are events or experiences other than the primary outcome(s) that will be used to evaluate the intervention(s), and that are specified in the study protocol. Enter the name of each secondary outcome measure of the trial, one at a time. Also provide all the timepoints at which this outcome is to be measured. Examples: Outcome Name: cardiovascular mortality, Timepoint: 6 months; or Outcome Name: functional status, Timepoint: 4 and 8 weeks

* All entries should accurately reflect the study protocol. If the study was approved by an ethics review board, entries should reflect the study protocol that received final approval from the ethics board.

C. Network of Member Registers

C.1 Network Structure

The Registry Platform seeks to develop common rules and expectations for registers, to achieve the following objectives:

- Achieve the registration of all interventional trials worldwide
- Make it easy for Responsible Registrants[1] and the public to know which registers meet international standards of acceptability
- Ensure that each trial is registered in the fewest number of registers necessary to meet applicable local and regional regulations, and is registered once and only once in any one register

To meet these objectives, the Registry Platform should establish a network of internationally acceptable registers ("Member Registers") that together are comprehensive but that minimize overlap. "Responsible Registrants" can register their trials *directly* or *indirectly* (see below) with Member Registers.

C.1.A Advice on composition of the network

Any register meeting WHO register membership criteria should be eligible to become a Member Register.

Member Registers: We expect that Member Registers will mainly be national or regional registers. Ideally, they will serve non-overlapping communities (defined as those that share language, regulatory, and/or cultural factors), but will agree to cooperate in areas of potential overlap. Individual countries, regions, or international scientific groupings may choose to form partnerships with existing registers or to develop their own registers. In the interests of minimizing the chance of duplicate registration and of conserving resources, the WHO should encourage the formation of the minimum number of Member Registers necessary to serve global needs.

Non-Member Registers: There exist many trial registers worldwide whose organizers may not wish their register to serve as a Member Register, or which may not qualify as a Member Register. These registers may serve other important functions, however. For example, a university may sponsor a register to increase participant recruitment in its own trials, or a disease-specific register may provide a central repository in which investigators can register their trials related to interventions for that disease.

Non-member registers should establish an agreement with a single Member Register to ensure that the trial is affiliated with only one Member Register. Non-member registers that establish a satisfactory formal agreement with a Member Register (criteria to be defined) should be designated Associate [Member] Registers of the WHO Registry Platform. Responsible Registrants may enter the Trial Registration Data Set in a Member Register (*direct registration*) and have that information sent to a non-member register, or the data could be entered first into an Associate Register and then be uploaded to the Member Register (*indirect registration*).

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[1] The "Responsible Registrant" for a trial is either the principal investigator (PI) or the primary sponsor, to be decided by an agreement between the parties. The primary sponsor is "the individual, organisation, group or other legal person taking on responsibility for securing the arrangements to initiate, manage and finance a study", and is ultimately accountable for ensuring that the trial is properly registered. For multi-center and multi-sponsor trials, it is the lead PI or lead sponsor who should take responsibility for registration. The responsible registrant should make every reasonable effort to ensure that a trial is registered once and only once in any one register, and that the trial is registered in the fewest number of registers necessary to meet applicable regulations

C.1.B Advice on operation of the network
The WHO should assist the appropriate parties in each member state (e.g., Member Registers, national authorities, journal editors) to issue clear guidance on the appropriate member register for Responsible Registrants in their region. The guidance will change as new Associate Register agreements are formed and as national and regional registers begin operation.

Responsible Registrants should enter the Trial Registration Data Set for an individual trial only once (including multicenter trials). Thereafter, the Trial Registration Data Set for that trial should be exchangeable electronically among all trial registers worldwide.

C.2 Membership Criteria

The SAG agreed to the following Register Membership criteria, but cautions that these criteria need further refinement and clarification before they should be put into place.

Register content

Registers must:

- Accept registration of interventional trials, as defined by the WHO Registry Platform;
- Have their own register-specific numbering schedule apart from the UTRN to identify individual register entries;
- Collect all items of the WHO Trial Registration Data Set, and must use the pick list choices if any are defined (e.g., Recruitment Status). Additional items (e.g., study sites) may be collected at the discretion of the register. Local format and presentation is at the discretion of the register, provided it can export and import the Trial Registration Data Set in the standard format.
- Assure informative entries in all content fields (eg, actual name of drug, not "a drug" in the intervention field);
- Agree never to remove a registered trial from the register;
- Display date of registration, and whether the item has been updated;
- Update entries on a regular basis (time interval and updating requirements to be determined), and must display the last update date. Comply with mechanisms for linking duplicate entries within and across registers, to ensure that all register-specific IDs that have been issued will continue to link to a valid entry;
- Be legitimate representatives of the community they claim to serve (e.g., registers claiming to be a "national" register must be recognized by the named nation)
- Establish agreements with non-member registers in their country or region to coordinate the exchange of the Trial Registration Data Set so that (1) Responsible Registrants have to enter the data set only once, and (2) multiple registrations will be minimized;

In addition, the WHO should develop criteria for acceptable arrangements between Member and non-member registers. Non-member registers with acceptable arrangements should be designated Associate Registers to indicate their participation in the Registry Platform.

Trial Deduplication
Registers must:

1. Commit to identifying entries in their register that refer to a single trial and commit to register modifications leading to only one valid register entry for each trial ("deduplication");
2. Commit to uploading to the central Reference Database in English the locally deduplicated entries for all interventional trials it registers, no later than some length of

time (to be defined) after registration in the Member Register (to allow for local deduplication, data verification, etc). If translation to English is required, a longer turnaround time (to be defined) will be allowed;

Technical*
Registers must:

1. Commit to uploading all required information to the Registry Platform according to the standardized interchange format (to be defined);
2. Commit to uploading or providing English-language content for all Registry Platform transactions (or commit to paying WHO for translation services);
3. Be able to perform required electronic "handshakes" and provide authentication information on all electronic transactions and processes with the WHO and other Registry Platform entities

* On a case by case basis, the WHO will work with registers to develop interim data handling procedures (e.g., comma-delimited files) for those registers not able to meet the technical standards required for Member Registers.

Quality Assurance
Registers must:

1. Have a mechanism for authenticating an individual or group submitting trial information (further details to be defined);
2. Have quality assurance procedures in place to ensure the validity of the registration data, and that only informative content is submitted (further details to be defined);
3. Have security and other provisions against data corruption/loss, including but not limited to a backup server and database.

Administrative
Registers must:

1. Be searchable by the public at no charge (either directly or through the Registry Platform Search Portal);
2. Clearly define the registrant group that the register serves (e.g., all trialists in a particular country or region) and must accept trials registered prospectively from all registrants from that community;
3. Fully disclose its ownership and not-for-profit/for-profit status
4. Comply with WHO Registry Platform policies prohibiting trial registration conflicts of interest:

   An entity has a trial registration conflict of interest if that entity stands to gain financially or otherwise from partial or selective registration of trials or trial information. For example, an entity that could benefit from registering only trials it expects to produce favourable results would have a conflict of interest. Another example of a conflict of interest would be an entity that could benefit from registering only some of the planned outcomes;

5. Comply with the WHO Registry Platform policy prohibiting receipt of grants, revenue (e.g., advertising), or any other income from entities that may have a trial registration conflict of interest as defined in Administrative Point 4;
6. Formulate and publicly declare an advertising code of conduct;

7. Decare itself a Registry Platform Member Register only when it is a member in good standing, and must remove all claims of membership from all websites and other electronic and non-electronic material if membership is revoked or expires
8. Commit to participating with the Network of Registers on evaluating and improving quality assurance, deduplication, and other issues, as decided by the Network
9. Commit to informing the WHO of all changes in its operations or otherwise that may be relevant to register membership
10. Agree to have its membership revoked or to reapply for membership, if a member register merges with another register or splits into more than one register
11. Agree that WHO will have the right to revoke membership if there is any breach of the terms of membership

Not required for membership

1. Entries into registers do not have to be in English, and entries may be displayed in any language, although uploads to the WHO must be in English (see Technical Point 2)
2. Registers are encouraged to but are not required to
    a. collect or store the study protocol itself
    b. collect and store protocol amendments
    c. provide links to or include trial results
    d. provide or link to an English version of the information they register
3. Registers are encouraged but not required to provide registration services free of charge or at minimal cost
4. Registers are encouraged to but do not have to offer fee waivers to trialists with hardship
5. Registers do not have to be non-profit organizations

D. Trial Deduplication

D.1 Background

One of the goals of the Registry Platform is to provide an unambiguous method for identifying individual trials worldwide. Achieving this goal is complicated because trials may be registered in more than one register, particularly as local regulations may require registration in non-member or multiple registers.

The process of deduplication requires skilled personnel assisted by computer programs that, at best, identify pairs of trials that *might* be duplicates. There is little research or evaluation on the accuracy of these computer systems, or on the overall accuracy of the process. In many cases, a human expert has to contact the providers of the records to resolve uncertainties, a labor-intensive process that can take considerable time. Familiarity with local sponsors, organizations, languages, etc. would be essential in many cases, complicating deduplication efforts for trials conducted in those countries.

The SAG endorses Registry Platform policies that will help to minimize the risk of duplicate trial registration. Platform policy should:

- Clearly identify the Responsible Registrant, and assign to the Responsible Registrant the responsibility for minimizing duplicate registration
- Define what constitutes a unique trial
- Standardize the Trial Registration Data Set to facilitate comparisions between register entries
- Provide a network structure of Member Registers that minimizes the overlap of constituencies, and increases the likelihood that Responsible Registrants register each trial without duplication
- Encourage new Member Registers to develop only if required to meet global registration needs
- Require Member Registers to perform deduplication of entries within their own registers
- Provide Member Registers a forum for sharing and developing best practices on deduplication and quality assurance
- Provide training and capacity building for trial registration worldwide

The SAG believes that the primary preventive strategy against duplicate registration is to assign an identifier to a trial at the earliest possible time, e.g., at the time of submission to the first ethics review board for that trial. Thereafter, all ethics submissions, participant enrollment, registrations, publications, etc. should use the initially assigned identifier. The logistics of implementing such a system both locally and globally are daunting, however. The SAG suggests that the WHO explore ways to assign a trial identifier as early in the trial registration process as possible, including the potential integration of ethics review and trial registration.

D.1.A Definition of Unique Trial

A trial is considered a "unique" trial if it is conducted according to a single document (the protocol) that describes its objective(s), design, methodology, statistical considerations, and organization. A multi-center trial is one that is conducted according to a single protocol but carried out at more than one site. Even if different versions of the protocol are implemented at each of the sites in a multi-center trial, they are all part of one unique trial and do not constitute separate trials.[2]

D.1.B Implementation of Trial Deduplication

The SAG appreciates the importance of trial deduplication, at the same time as it recognizes the difficulties. The SAG supports the approach of breaking the deduplication task down into two levels:

1. Local Deduplication: The best strategy for deduplication is prevention. Member Registers should verify that each new addition to its own register is not likely to be for a trial that has already been registered *within* that same register. Many existing registers already do local deduplication. All deduplication results should be shared with all involved parties (registers and registrants) so that future duplicate registration may be reduced. Member Registers should exchange information about experiences and approaches, so as to improve their overall deduplication performance.
2. Global Deduplication: No entity currently performs deduplication of register entries *across* registers. The SAG favors the WHO taking on this task, by providing a clearinghouse database for entries from all Member Registers, and working with existing groups who have extensive knowledge and prior experience with deduplication to develop best practices.

In partnership with registers administrators and other experts, the WHO should continue to investigate methods for quicker and more accurate deduplication, including but not limited to computational approaches, data standardization and coding, and manual approaches.

D.1.C Universal Trial Reference Number

Global deduplication will be the responsibility of WHO, which will compare each register entry against entries from all other registers. The SAG considered various approaches to doing this. One possibility is to run a web-based search across all Member registers to identify register entries that appear to be associated with each trial.

A large majority of the SAG endorsed the WHO assigning a Universal Trial Reference Number (UTRN) to each unique trial as determined by the process of global deduplication. This reference number serves a function -- cross-referencing entries across trial registers -- that no existing number does. The consensus was that the overall benefits of having one global reference number for each trial that is determined (as best we can) to be unique outweighs other potential issues related to the introduction of a new number. The minority opinion was that a new number would introduce more confusion than not.

It is unclear how much time the process of global deduplication will take. The WHO should aim for the quickest turnaround possible,, combined with the desired level of accuracy. A trial should be considered fully registered when it is registered in the Primary Register, so that assignment of the UTRN will not delay the initiation of recruitment for a trial. The UTRN should be relayed back to all registers and registrants affiliated with the trial.

E. Coding and Data Interchange

E.1 Coding of Trial Registration Data Set Items

Coding the values of key items in the Trial Registration Data Set (e.g., Item 13 Intervention name, Item 12 Health condition or problem studied, and Item 19 Primary Outcome Measure(s)) using standard vocabularies will allow for precise searching, which will be increasingly important as more trials are registered. The WHO should consider coding key fields of the Trial Registration Data Set and returning the coded terms to the Member Registers. The WHO should continue to consult coding experts to develop an approach to maximizing the utility of register entries in Member Registers.

Concern was raised by some SAG members that registering all interventional trials would result in a "clogged system" overwhelmed by many small, early phase studies. The fear was that potential trial participants may search for trials on a particular health condition and identify early phase studies that are not of interest. However, if certain fields in the Trial Data Set are coded using standard vocabulary that has a hierarchy of related concepts (e.g., MeSH), search portals can filter out trials with characteristics typical of early phase studies, and thus filter out unwanted trials.

E.2 Data Interchange Standards

Responsible Registrants will enter the Trial Registration Data Set only once, and that thereafter, the information should be exchangeable electronically among all relevant data systems. To achieve this data interchange, the Registry Platform should define a data interchange standard reflecting the Trial Registration Data Set, but only after due diligence in exploring and harmonizing with related information standards that already exist. These standards include those by HL-7, CDISC, and the BRIDG group, EMEA, and others from both the commercial and non-profit sectors. Care should also be taken to set the technical complexity of the standard at a level appropriate to need, and to provide technical assistance to registers (e.g., from developing countries) that may not have the technical expertise to implement the data interchange standard.

Glossary

Interventional Clinical Trial	Any research study that prospectively assigns human participants or groups of humans to one or more health-related intervention to evaluate the effect on outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral approaches, process-of-care changes, preventive care, diagnostic procedures.
Data Interchange Standard	A set of rules for sending information between machines. Includes agreement and standardization on the concepts exchanged (e.g., "primary sponsor"), and agreement and standardization on the structure of the actual message that is exchanged.
Deduplication	The process of determining whether two sets of trial information belong to the same trial or whether they belong to 2 *unique trials* (see below). Deduplication can happen within registers (local deduplication), as well as among registers (global deduplication).
Direct Registration	Occurs when a Responsible Registrant submits the Trial Registration Data Set of a trial to a Member Register for the purpose of registering that trial
Indirect Registration	Occurs when a Responsible Registrant submits the Trial Data Set of a trial to an Associate Member Register, which then forwards that Data Set to the appropriate Member Register for registration of that trial
Member Register	A register that meets all Registry Platform criteria for international acceptability. Member Registers belong to the Network of Member Registers.
Primary Register	The Member Register in which a trial is first registered.
Responsible Registrant	The "Responsible Registrant" for a trial is either the principal investigator (PI) or the primary sponsor, to be decided by an agreement between the parties. The primary sponsor is "the individual,organisation, group or other legal person taking on responsibility for securing the arrangements to initiate, manage and finance a study" (as defined in Trial Registration Data Set), and is ultimately accountable for ensuring that the trial is properly registered. For multi-center and multi-sponsor trials, it is the lead PI or lead sponsor who should take responsibility for registration. The responsible registrant should make every reasonable effort to ensure that a trial is registered once and only once in any one register, and that the trial is registered in the fewest number of registers necessary to meet applicable local and regional regulations.
Standard Vocabulary	A set of terms covering a domain of knowledge (e.g., medicine) that can be used as a shared way to describe that domain of knowledge. The terms may be related to each other in meaningful ways.
Unique ID	A unique identifier assigned by a register to each of its entries to identify individual register entries. With local deduplication, the register-issued unique ID will usually relate to a single, unique trial. However, if that trial is also registered in another register, the trial will also have another register-issued unique ID assigned by the other register. Thus, a register-issued

	ID will usually relate to a single, unique trial within that register but a single, unique trial may have more than one register-issued unique ID.
Unique Trial	A trial is considered a single trial if it is conducted according to a single document (the protocol) that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. A multi-center trial is one that is conducted according to a single protocol but carried out at more than one site. Even if different versions of the protocol are implemented at each of the sites in a multi-center trial, they are all part of one trial and do not constitute separate trials
UTRN	Universal Trial Reference Number, a number that the WHO Registry Platform issues for each trial deemed to be unique across Member Registers. The UTRN would be used to cross-reference entries for that same trial across multiple registers. Each single, unique trial will have one UTRN, and each UTRN will relate to a single, unique trial worldwide.

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- **Deborah Zarin**, ClinicalTrials.gov, Bethesda, Maryland, United States of America

資料 3

国民向け、臨床試験の啓蒙・普及に関する学習、Q/A、機能の概要

1. 臨床試験について学習
・臨床試験が必要な理由
・科学と倫理、関連する法規
・介入の例
・被験者の安全性の確保
・臨床試験の登録について
・臨床試験の結果の公表について
・用語の説明(同意、ヘルシンキ宣言、倫理委員会、臨床試験実施計画書、比較臨床試験、介入、試験デザイン、割り付け、無作為化、盲検化、主要評価項目、副次評価項目、責任研究者、など)

2. Q and A 例
・臨床試験とは何ですか?
・臨床試験には誰が参加するのですか?
・なぜ臨床試験に参加するのですか? 臨床試験に参加するメリットは何ですか?
・臨床試験では参加する被験者の権利が保護されていると聞きましたが、'同意' とは何ですか?
・臨床試験では参加する被験者の安全はどのように保護されているのですか?
・誰が臨床試験を行うための資金を拠出するのですか?
・臨床試験の中ではどのようなことがなされ、参加する被験者にどのようなことが起こるのですか?
・臨床試験実施計画書とは何ですか?
・比較臨床試験とは何ですか? 比較をしない臨床試験はあるのですか?
・対照とは何ですか?
・臨床試験にはどのような種類があるのですか?
・臨床試験に参加した被験者は試験の途中で臨床試験からの参加をとりやめることができるのですか?
・臨床試験の結果はどのように利用されているのですか? 個人情報の保護はどのようになされるのですか?
・現在計画されている、または実施中の臨床試験について知ることができますか?
・臨床試験の中で予想されたメリットとは逆に試験に参加したときにかかっていない病気にかかったなど良くないことが起こることもあるのではないかと思いますが、そのときは被験者には何か保障があるのでしょうか?

3. システムの機能

・臨床試験の啓蒙・普及に関する学習のための解説・説明

・臨床試験に関するQ/A形式の説明

・日本で現在登録されている臨床試験の検索・照会(日本語)

・日本で現在公開されている臨床試験の結果の検索・照会(日本語)

・世界で現在登録されている臨床試験の検索サイト(Member register のどれか)へのリンク

・世界で現在公開されている臨床試験の結果の検索サイト(Cochran center ?)へのリンク

厚生労働科学研究費補助金（厚生労働科学特別研究事業）
分担研究報告書

臨床研究登録情報検索のためのポータル・サイト基本設計に関わる調査研究

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研究要旨

臨床研究（治験）登録のメリットとして１．出版バイアスの防止、２．ネガティブデータの活用、３．臨床試験参加者募集の促進等があげられる。臨床研究（治験）登録の推進と日本における一般市民への登録制度の普及啓発のため、現在運用されているＵＭＩＮセンター、ＪＡＰＩＣ及び、今後運用予定の日本医師会治験促進センターの３機関の登録システムに登録されている登録データの情報提供用横断検索Portal Site開発のための調査・分析を行った。

１．システム開発の目的

本システムは日本語で利用できる一般市民（日本国民向け）を対象に、三機関の３つの登録システムに登録されているデータの串刺しポータル（検索）機能を中心として、国民への普及啓発機能を追加したシステムを構築することを目的とする。したがって、三機関のデータをありのままに検索して表示するものであり、表示にあたって、異なる要素を持つ３つのシステムの統合をはかるものではなく、ポータルサイトで表示する項目も三機関の項目の共通化をはかるものではない。
また、WHOで現在検討中ICTRPのmember register, minimum data setなどとの整合性をとるものではない。

２．日本における登録システムとの連携

本システムは、日本における登録システムにおける臨床治験登録情報に関する一般市民への広報を目的とした臨床試験登録情報のPortal siteの構築である。
一般市民が本システムの情報検索機能を利用し、UMIN、日本医師会、JAPICの三機関に登録されている臨床試験の検索を一元的に容易に行うことができるためには、システム連携が必要である。

これを実現するために、本システムの他システム連携インターフェースの調査及び将来的構築のための概要設計を本研究では検討する。具体的には、以下の機能について検討する。

・各機関のシステムで登録された臨床治験登録データの情報属性の定義及び提供方法についての調査／検討
・各機関のシステムで登録された臨床治験登録データの検索・参照のための検討

・各機関のシステム環境の調査及び調査とPortal siteのシステム環境の検討

３．研究方法

横断検索を行うためには、検索対象機関である三機関（UMIN、日本医師会、JAPIC）の協力を得ることが重要となってくる。

そのため、システム設計をするにあたり、治験データをどのような形であれば提供いただけるか、利用可能かを実現方法を検討するにあたり考慮した。

３．１三機関登録システム調査・分析

三機関の登録システムの現行システムの調査・分析を行う。

３．２．実現方法の検討

実現方法を検討する上で以下の点を重視した。

(1)三機関に負担がかからない方法か。

提供いただく機関に対し、費用面、相手機関側にセキュリティ上受け入れられない内容等の無理をお願いすることは、運営に負担がかかる。そのような方法は事業として無理が生じる。

(2)横断検索データはリアルタイム性が必須要件であるかどうか。

研究班では、データがリアルタイム性を要求するものかどうかの検討を行った。リアルタイム性が要求されるものであれば、SOAPによる個別問い合わせ方式によるデータ交換がある。しかし、SOAPメッセージはXMLにてネットワーク上で情報交換するので、例えばパスワード情報等を流した場合、盗聴される危険性がある。また、リアルタイム性を実現する個別問い合わせ方式の場合、共通インターフェースや共通データ項目を決めることが必要だが、これは本研究の目的ではなく、加えてSOAPメッセージのやりとりで必要なアダプタを各機関の既存システムサーバに組み込んだり、または、各機関に別途連携サーバを設置しやりとりを行うにしてもセキュリティポリシー上協力を得るのが難しい機関もあり、現段階での採用は難しいと判断した。

(3)データ交換に関わるシステムの機密性はどのように保つか。

本システムで扱うデータは全て公開データであり、個人情報保護法など情報漏洩への対応を目的としたセキュアなネットワーク構築は行わないものとする。

３．３．データレベルについて

横断検索で提供するデータは一般にインターネット上に公開されているオープンな情報である。そのため、データを交換する際、盗聴される危険性等を考慮し、インターネットVPN等専用線利用によるクローズなネットワークの採用の意見も出されたが、本研究班ではデータの三機関からのデータ交換の際、費用対効果を考慮し、ネットワークをクローズにする必要はないとの結論に達した。

３．４．データ交換方式

三機関からのデータ提供していただく方式を以下の三方式を基本に検討を進めた。

３．４．１．データ蓄積型方式

各臨床試験システムからデータをバッチ処理で横断検索Portal Siteサーバのデータベースに取込みます。一般市民からの検索アクセスがあった場合、横断検索Portal Siteサーバのデータベースから検索を行い、すみやかに返し、表示を行う。

(1)長所
検索時、各システムに負荷をかけない。
各システムがダウンしていても、検索結果の提供が可能である。
(2)短所
三機関分のデータを格納するディスクが必要となる。また、バッチ処理時に取り込むデータが多量である場合、各システムに負担がかかる。また、三機関でデータ更新があった場合、変更がリアルタイムに反映されない。

３．４．２．個別問合せ方式

一般市民からの検索要求毎に、各機関のWebサーバに対し、個別問合せを行い結果を一覧で表示を行う。
(1)長所
臨床研究情報データベースを保持しないので大容量ディスクが不要で、各システムの情報更新にリアルタイムに対応が可能である。
(2)短所
検索毎に、各システムに負荷がかかる、各システムがダウンしているとその部分のデータの検索ができない。また三機関各システムWebサーバに、HTTPによる個別問合せ機能プログラムの設置や、XMLを利用したSOAPの場合はポータル間でアダプタと共通I/F間インターフェースを設計し構築する必要がある。

３．４．３．データベースリンク方式

(1)長所
臨床研究情報データベースを保持しないので大容量ディスクが不要で、各システムの情報更新にリアルタイムに対応が可能である。
各システムに本システムの為の機能を保持する必要がない。
(2)短所
検索毎に、各システムに負荷がかかる。
各システムがダウンしているとその部分のデータの検索ができない。各システムでデータベースの構成を変更した場合、影響を受ける。
データベースリンクの三機関各システムの許可が必要である。

以上、三方式の検討を行った結果、①治験データの入力は常時行われるものではなく、本システムはデータのリアルタイム性が必須として求められるものでなく、②データがテキストデータだけに限られ、バッチで取り込むデータ更新件数が少ないこと、③三機関のサーバが万が一ダウンしていても検索可能であり、④個別問合せ方式にサイトのポリシー上協力を得るのが難しい機関があったことを考慮し、研究班では、データ蓄積型方式を採用した。しかし、今後、SOAPを利用したリアルタイムの検索等の実証試験も必要と思われる。
注:SOAPポータル間インタフェース方式では、リモート環境でのアクセス技術として、インターネット環境(TCP/IP)を介して接続されたプログラム間で相互アクセスを行うために利用される。

３．５．データの定義

三機関からのデータ取り込みにあたり、各機関とデータの定義を行うが、共通化は図らない。尚、本システムで扱うデータは全て公開データであり、個人情報保護法など情報漏洩への対応を目的としたセキュアなネットワーク構築は行わないものとする。
(1)データ取込
データを三機関側から送信するか、もしくは、検索Portal Siteのシステムが取り込みにいくか検討された。三機関側から送信する場合

悪意ある第三者からのなりすましによる送信により異常データが投入される可能性がある。このため、科学院側から三機関側へデータを取り込みに行く方式を採用することとなった。尚、接続サーバの制限、SSL等により、アクセス制限・認証を設ける必要がある。尚、データ交換にはインターネットを利用するが、三機関の環境はそれぞれ異なるため、暗号化通信や認証等の技術は、費用他効果も考慮し、構築にあたっては今後調整が必要である。

(2)三機関からの提供データ

三機関から提供される治験登録データは、新規登録・更新データの差分データを負荷のかからない時間帯にバッチにより、取り込み処理を行う。提供データの生成機能は各機関で仕様が異なり、各機関のセキュリティポリシの問題もあり、必要な場合は各機関にて開発を行うことになるが、費用の問題もあり今後検討が必要である。

(3)改ざんについて

不正侵入に対する検知や、改ざん等に対する防御に対する必要性ついては、費用対効果の問題もあり、どこまで行えるかまた必要なのかは、今後議論が必要であろう。

ただ金融システムのようなわずかなシステムダウンでも社会的な影響度が高いシステムではなく、本Portal Site情報検索サイトであり、万が一システムが利用できない場合でも、各機関の治験登録システムのSiteにアクセスできれば情報を入手できることも考慮し、構築することになる。

4．システム概要

本システムは、一般市民への情報提供として、公共性の高いインターネットを採用するが、システムの安全性（セキュリティ）と情報の取扱については費用対効果を考慮し構築を行う。本システムを設置する国立保健医療科学院の策定した情報セキュリティポリシに則り、構築する。

一般市民は本システムの利用をブラウザで行うことができる。

4．1．性能要件

(1)性能要件

情報提供システムはアクセス時の処理負担増による、システムへの影響がないよう考慮し、構築をすることが必要である。また、今後の利用機会の増加や、ソフトウェアのバージョンアップにより機器の負荷が増える傾向にあり、インターネットアクセスや運用面で性能不足が生じる恐れがある。このため、高性能の機器あるいは高機能の検索エンジンを導入することにより、スループット向上を図り、アクセスの遅延は解消されうる。しかし、本研究班ではシステム設計にあたり現行治験登録システムのアクセス状況や費用対効果を考慮し、性能よりも費用を重視し設計を行うこととした。

(2)信頼性

本システムの導入に伴い、インターネット利用による横断的なデータの検索を行うことにより、一般国民が治験登録情報の収集をしやすくなるため、今後の臨床研究（治験）登録制度の今後を考える上で、本システムの重要性は重要性が増えると思われる。

このため、障害発生時のサービス停止の回避を重視するのであれば、サーバを冗長化（もしくはクラスタ化）することにより、システムの信頼性を向上させることができ、バージョンアップやパッチ適用等、メンテナンス時もサービス停止期間を短縮することも可能で

ある。
しかし、本ジズテムでは財政負担軽減のため、信頼性よりもなるべく費用のかからないシステム構築を求められた、そのため、設計にあたり費用対効果を考慮し、信頼性よりも費用を重視し設計を行うこととした。
(3)システム及び機器基本要件
以下にシステム及び機器に求められる条件を記載する。
①本システム導入後の運営、管理、オペレーションについてシステム管理者およびエンドユーザが容易に理解できる設計を考慮すること。
②システム仕様は業界標準に準拠し、拡張性及び互換性に優れたものであること。

４．２．構築・運用
本システムは国立保健医療科学院に構築する予定であるが、構築にあたっては既存の稼動システムに影響を与えることなく、また円滑に導入することが求められる。また、近年のシステムのオープン化により、システムの構築はマルチベンダー構成により構築を行なうことが多いが、特にシステム障害時の際、インテグレーターとして、関連する業者間の調整を確立し、速やかに対応できることが重要である。
また、本システムでは財政負担を軽減し、費用対効果を考慮した設計を行う。本院にある機器システムを利用可能な場合は、極力これを利用し、無駄のない構築を図ることはもちろんであるが、とくに運用面の人的な負担軽減を考慮した機能選択と、開発費用の低減を重視し、開発項目、機器の絞込み等を積極的に行うこととする。
(1)システムに関して、費用対効果を考慮しながら、システムの構築及び安定的な運用を行うための体制を確立する。
(2)導入スケジュールの計画に際し、本院ネットワークシステムへの接続については、本院システム管理者と協議を行う。
(3)本院に対する窓口の一本化及び供給者間の技術的な問題の調整機能を整備する。

４．３．利用者と試験環境
当システムの利用者環境を次のように想定し、試験対象とする環境を提示する。
当システムを利用するためのクライアントプログラムは、一般的なインターネット利用者のブラウザである。
本システムの利用対象者のOS、及びブラウザは次のものを想定する。
(1)PC/AT互換機
OS：Microsoft WindowsXP
ブラウザ：IE6.x sp2、Netscape7.x
(2)MAC互換機
OS：Mac OS X
ブラウザ：IE:5.5SP2、Netscape7.x、Safari
上記以外のウェブ・ブラウザソフトでの表示および動作保証については、範囲外とする。

５．機能概要
本システムで提供する機能を記述する。三機関の３つの登録システムに登録されているデータの串刺しポータル(検索)機能をはじめ、データ管理／収集機能、管理機能を有する。
本システムにおける検索対象のデータは全てテキストであり、データベースに格納されているデータでHTMLファイルも対象としていない。利用者は本Portal Siteより指定した項目より中間一致による検索を行うことができるよう設計する。医学辞書等を備えたシソーラ