



CDISC INTERCHANGE 2006

WHO International Clinical Trials Registry Platform

Ghassan Karam

Information Technology Officer

Department of Research Policy and Cooperation

World Health Organization

Geneva, Switzerland

April 26, 2006



Outline

- Background
 - Registry Platform Overview
 - Trial Registration Data Set
 - Register Network
 - Universal Trial Reference Number (UTRN)
 - Search Portal
 - Data Interchange - Coding
 - Summary
-



Need for Trial Registration and Reporting

- Clinical trials give valuable evidence on health interventions
 - They give extensive media coverage of several cases of selective reporting of results
 - Help ensure a full unbiased public record on safety and effectiveness
 - Strengthen public trust, avoid drop in participant enrollment
-



Current Policies, Growing Needs

- ❑ Many journals in addition to the International Committee of Medical Journal Editors (ICMJE) now accept only registered trials for potential publication
 - ❑ Local and national laws beginning to require trial registration
 - ❑ Many new and existing registers serve many different constituencies and needs
 - ❑ Need for global coordination
-



Why World Health Organization?

- Global, neutral, independent body with convening capacity (i.e. World Health Assembly resolutions)
 - Role in setting norms and standards in research, policy and practice
 - Good Clinical Practice, ethics guidelines, classification standards (e.g., ICD)
 - Contributes to capacity building (i.e. in developing countries)
 - Political legitimacy, **accountable to 192 member States**
 - Commitment to achieving equity in health
-



Launching of the Registry Platform

- Series of formal and informal meetings since 2003

 - Aug 2005 – Formal launch of International Clinical Trials Registry Platform secretariat
-



Outline

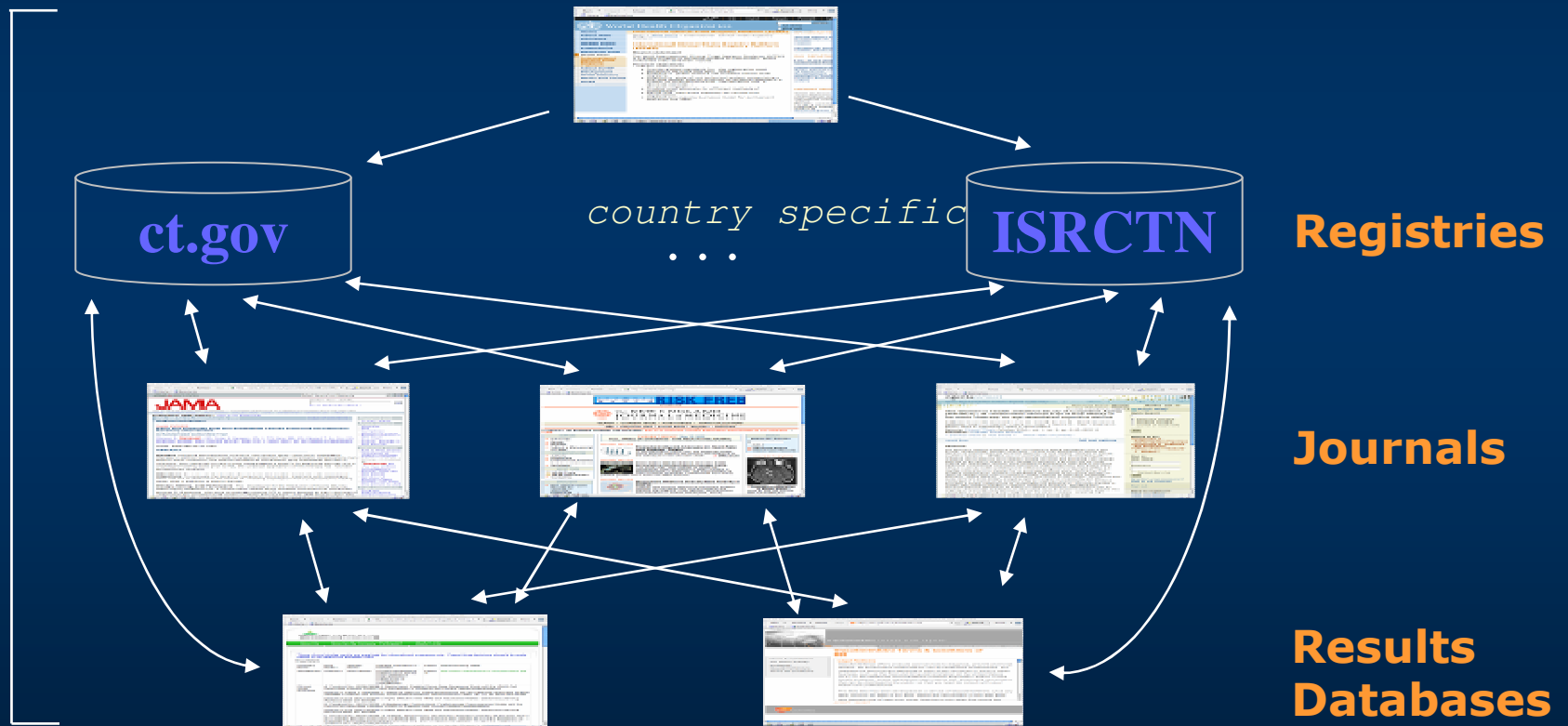
- Background
 - Registry Platform Overview
 - Trial Registration Data Set
 - Register Network
 - Universal Trial Reference Number (UTRN)
 - Search Portal
 - Data Interchange - Coding
 - Summary
-



Registry Platform Overview

WHO Search Portal

WHO International Clinical
Trials Registry Platform





Which Trials Must Register?

- Registration of all interventional trials is a scientific, ethical, and moral responsibility
 - Any research study that prospectively assigns humans or groups of humans to health-related interventions

 - Includes Phase I to Phase IV trials
-



Outline

- Background
 - Registry Platform Overview
 - Trial Registration Data Set
 - Network of Member Registers
 - Universal Trial Reference Number
 - Search Portal
 - Data Interchange - Coding
 - Summary
-



Trial Registration Data Set

- 1. Primary Register and Trial ID#**
 - 2. Date of Registration in Primary Register**
 - 3. Secondary ID#s (e.g., study #, ERB #)**
 - 4. Source(s) of Monetary or Material Support**
 - 5. Primary Sponsor**
 - 6. Secondary Sponsor(s)**
 - 7. Contact for Public Queries**
 - 8. Contact for Scientific Queries**
 - 9. Public Title**
 - 10. Scientific Title**
 - 11. Country of Recruitment**
 - 12. Health Conditions or Problems Studied**
 - 13. Intervention(s)**
 - 14. Key Inclusion and Exclusion Criteria**
 - 15. Study Type**
 - 16. Date of First Enrolment**
 - 17. Target Sample Size**
 - 18. Recruitment Status**
 - 19. Primary Outcome(s)**
 - 20. Key Secondary Outcome(s)**
-



Outline

- Background
 - Registry Platform Governance and Structure
 - Registry Platform Overview
 - Trial Registration Data Set
 - Register Network
 - Universal Trial Reference Number
 - Search Portal
 - Data Interchange - Coding
 - Summary
-



Register Network Structure

- Primary Registers (relatively few)
 - Should be national, regional, or international (max of 1 per country)
 - Must be open access
 - Perform quality assurance, deduplication, accountability, data interchange
 - Submit Registration Data Set directly to WHO
 - Associate Registers (relatively many)
 - Must be affiliated with a Primary Register
-



Outline

- Background
 - Registry Platform Governance and Structure
 - Registry Platform Overview
 - Trial Registration Data Set
 - Register Network
 - Universal Trial Reference Number (UTRN)
 - Search Portal
 - Data Interchange - Coding
 - Summary
-



Universal Trial Reference Number (UTRN)

- New number to be issued by WHO to each trial deemed unique across registers
 - Unique trial: conducted according to a single protocol document

 - Used to cross-reference entries for same trial across multiple registers
 - Each single, unique trial will have one UTRN
 - Each UTRN will relate to a single unique trial worldwide
 - No current trial ID number performs this function, promotes integrity of entire system
-



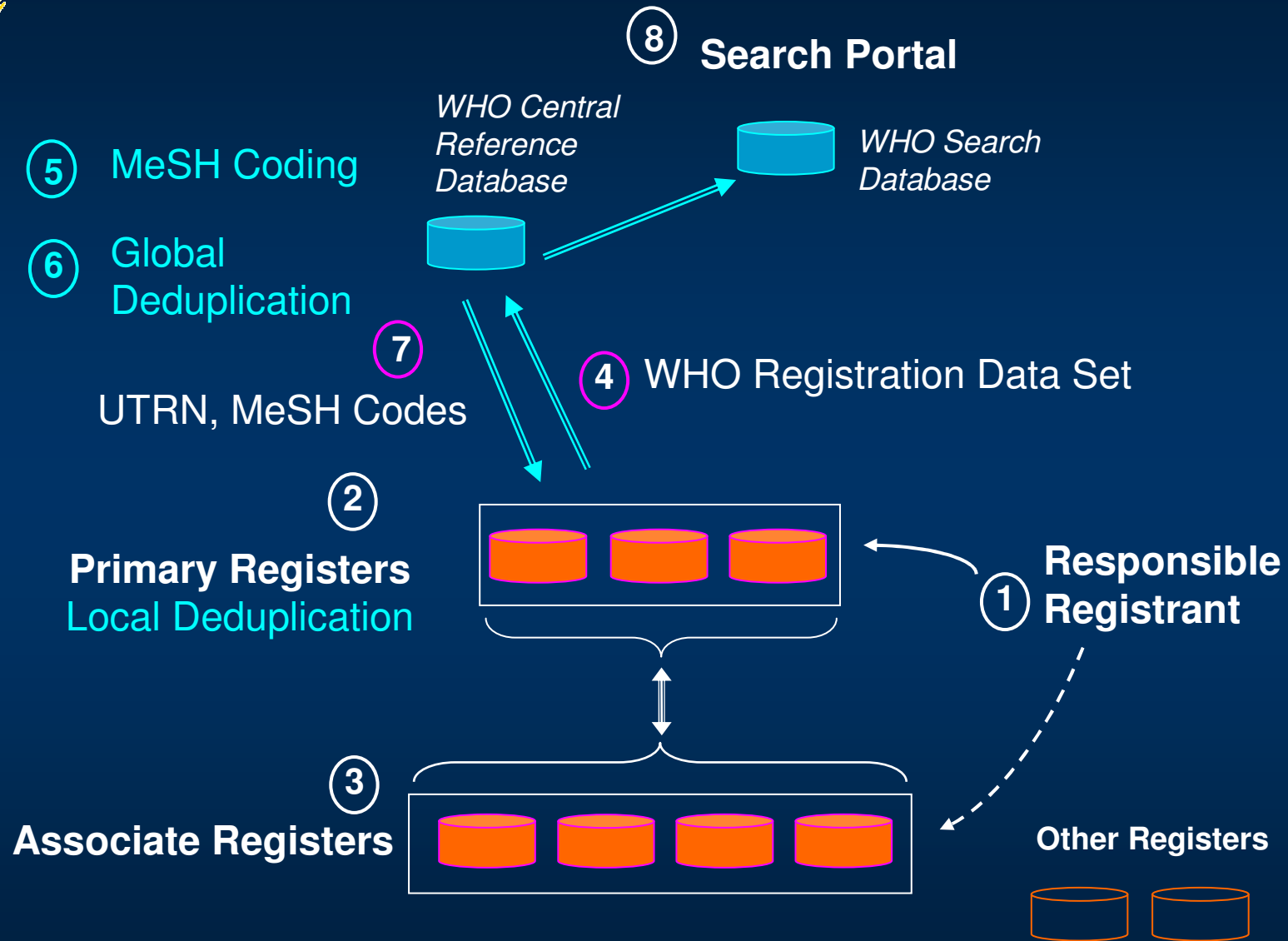
Outline

- Background
 - Registry Platform Governance and Structure
 - Registry Platform Overview
 - Trial Registration Data Set
 - Register Network
 - Universal Trial Reference Number
 - Search Portal
 - Data Interchange - Coding
 - Summary
-



Open Access Search Portal

- Searches all Primary Registers
 - Provides gateway to trial information worldwide
 - Searches by
 - UTRN
 - All items of WHO Registration Data Set
 - Conditions, interventions, outcomes will be coded in MeSH to improve retrieval accuracy
 - Will have patient and scientist versions
-





Outline

- Background
 - Registry Platform Governance and Structure
 - Registry Platform Overview
 - Trial Registration Data Set
 - Register Network
 - Universal Trial Reference Number
 - Search Portal
 - Data Interchange - Coding
 - Summary
-



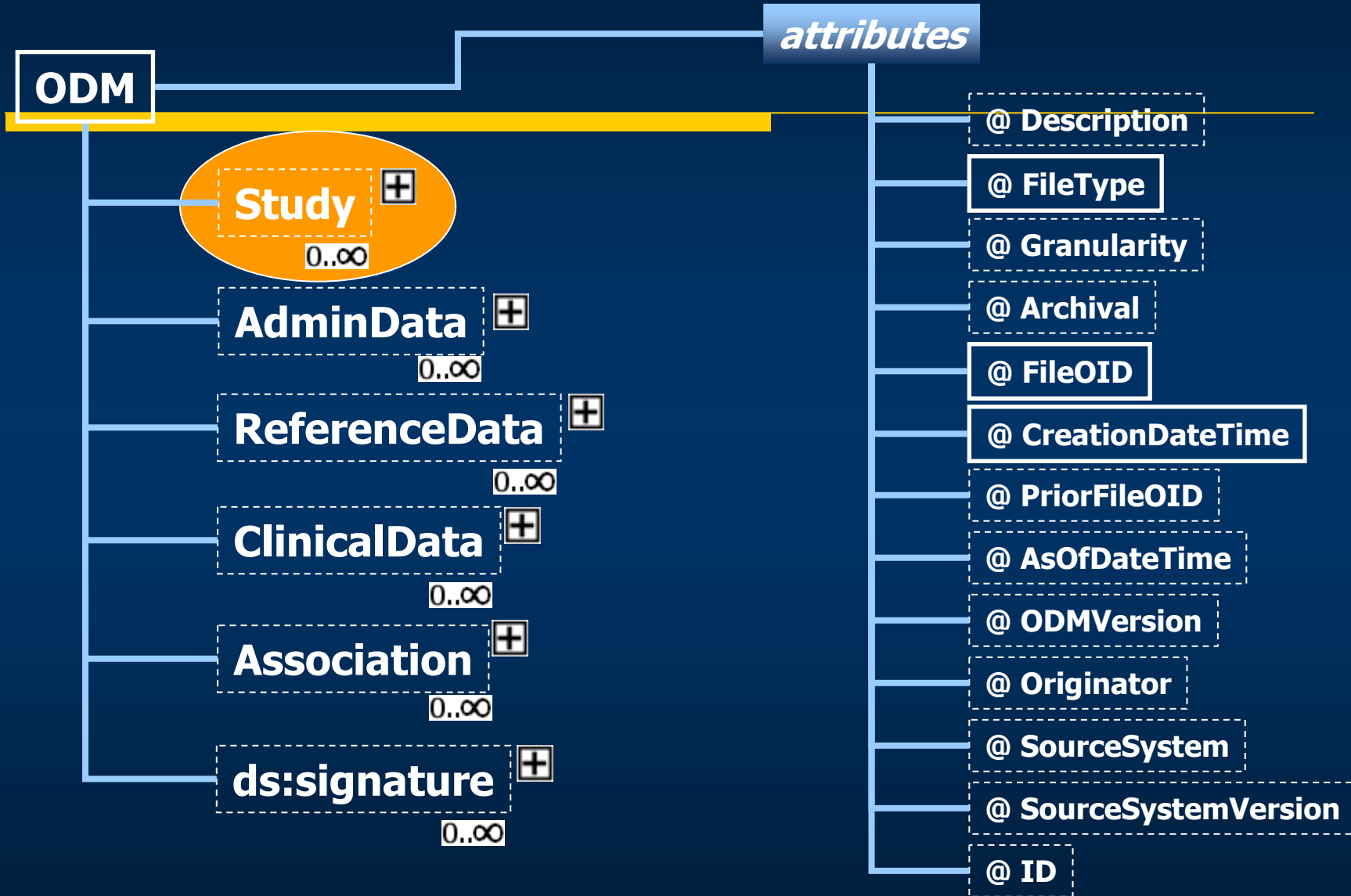
Data Interchange Standard(1)

□ Currently defining XML standards for the data interchange of the 20 item WHO Registration Data Set

- CDISC is leading the effort, working with HL7, BRIDG, etc.
 - The format is an XML DTD that falls out of a refinement of the CDISC ODM
 - Some fields map to CDISC SDTM
 - Some fields map to HL7
 - Some fields map to IEEE standards
-

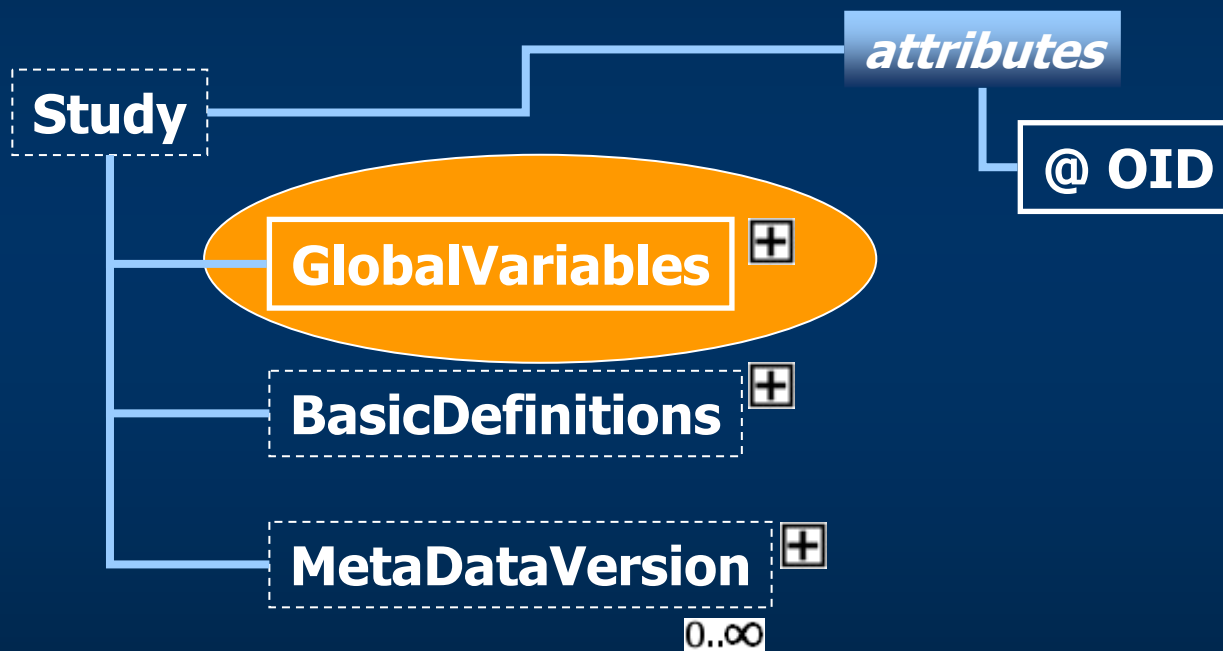


CDISC ODM Element





Study Element





GlobalVariables Element

GlobalVariables

StudyName

StudyDescription

ProtocolName

WHO Elements

```
<GlobalVariables>
  <StudyName>CDISC Example Study</StudyName>
  <StudyDescription>A simple trial to demonstrate the end-to-end
application of the CDISC Standards</StudyDescription>
  <ProtocolName>CDISC Example Study</ProtocolName>
  <!-- WHO Trial Registry Elements Here -->
</GlobalVariables>
```



Data Interchange Standard(2)

- Currently planning to introduce more structure into some fields, starting with
 - Inclusion/exclusion criteria: add
 - Age: (AgeMin AgeMax)
 - Gender: has a controlled terminology in SDTM
 - Sources of monetary support: create a pick list (e.g. foundation, pharmaceutical company, national health institute)
-



Data Interchange Standard(3)

- Interchange standard should be doable by the average IT shop, or the average register
 - WHO technical assistance will be offered for those who need it
 - Should be open source, non-proprietary
 - Next steps in the coming 3 months
 - testing interchange with Registers Working Group
 - planning adoption over the rest of this year
-



Coding - Medical Vocabulary

- Planning to code key scientific fields
(Interventions, conditions, primary outcomes)
 - MeSH best match to our use case of the Search Portal
 - MeSH designed for biomedical bibliographic uses
 - Other vocabs considered (SNOMED, ICD)
 - Open Questions
 - **costs vs. benefits of coding?**
 - **which is best target vocabulary in long run?**
 - **different vocabularies for different fields?**
-



Outline

- Background
 - Registry Platform Governance and Structure
 - Registry Platform Overview
 - Trial Registration Data Set
 - Network of Member Registers
 - Universal Trial Reference Number
 - Search Portal
 - Data Interchange - Coding
 - Summary
-



Summary - WHO Registry Platform...

- **Has finalized required registration items (20)**
 - **Is establishing a network of Primary and Associate registers to coordinate registration worldwide**
 - **Will perform global deduplication of trials and issue UTRNs to globally unique trials**
 - **Will launch a one-stop search portal of Primary Registers**
 - **Is defining standards for minimum reporting of results**
 - **Is defining technical standards for data interchange on trial registration and reporting**
-



Conclusion

- ❑ Clinical trials transparency and public trust is a global issue
 - ❑ WHO taking lead on policy and technical platform for coordinated trial registration and reporting worldwide
 - ❑ The overriding principle is to promote scientific and ethical integrity
 - ❑ Input from all stakeholders is welcome
-



WHO Registry Platform Team

□ Project Coordinator

- Ida Sim

□ Staff

- Esther Awit
- An-Wen Chan (short-term)
- Ghassan Karam
- Patrick Unterlerchner

□ Other WHO

- Metin Gülmezoglu
- Tikki Pang
- Luis Gabriel Cuervo (PAHO)

<http://www.who.int/ictrp>
