# Topics

- A regional network of Clinical Trials Registries
- Requirements and compliance with ICTRP standards and best practices
- How the regional platform is being developed

# I am Luciano Ramalho...

- A new hire at BIREME
  - consultant since Aug. 2009, employee Jan. 2010
  - software development supervisor
  - report to Renato Murasaki (MTI)
- A veteran of the Web
  - since 1994, as CTO of Brasil Online at Abril S/A, the 1st national news and entertainment portal
- A veteran of Open Source
  - active contributor since 1998
- Library and IS degree (almost)

# A regional network of Clinical Trials Registries

bvs biblioteca virtual em saúde

BIREME OPAS OMS

# Biblioteca Virtual em Saúde

login para serviços personalizados

## Pesquisa na BVS

Entre uma ou mais palavras | Todos os índices | Todas as fontes | Pesquisar

método: integrado por palavras por relevância google

pesquisa via descritores DeCS/MeSH

## Destaques


1 2 3 4

## Twitter

BIREME e BVS no Twitter. Siga e informe-se

## Redes

Países

Temas

BVS

Países

- Angola
- Argentina
- Barbados
- Belize
- Bolívia
- Brasil
- Cabo Verde
- Chile
- Colômbia
- Costa Rica
- Cuba
- El Salvador
- Equador
- Espanha
- Guatemala
- Guiné-Bissau

## Fontes de Informação

### Literatura Científica e Técnica

**Ciências da Saúde em Geral**
LILACS, IBECS, MEDLINE, Biblioteca Cochrane, SciELO

**Portal de Evidências**
Revisões Sistemáticas, Ensaios Clínicos, Sumários de Evidência, Avaliações Econômicas em Saúde, Avaliações de Tecnologias em Saúde, Diretrizes para Prática Clínica

**Áreas Especializadas**
ADOLEC, BBO, BDENF, CidSaúde, DESASTRES, HISA, HOMEOINDEX, LEYES, MEDCARIB, REPIDISCA

**Organismos Internacionais**
PAHO, WHOLIS

**LIS- Localizador de Informação em Saúde**

**DeCS- Terminologia em Saúde**

**Acesso a Documentos**
SCAD- serviço de cópia de documentos, Catálogo de revistas científicas

### Diretórios, Portais

**Diretório de eventos**

## Newsletter BVS

Rede de Notícias BVS

"Proteção social em saúde" norteia o programa científico do CRICS9

América Latina e Caribe compartilham acesso livre à Biblioteca Cochrane na BVS

BVS publica hotsite sobre Urbanismo e Vida Saudável no Dia Mundial da Saúde 2010

Saúde da Mulher e Saúde Materno-Infantil na BVS se fortalecem no âmbito regional

Capacitações LEYES promovem o desenvolvimento da BVS Legislação em Saúde

Organización Panamericana de la Salud
Oficina Regional de la Organización Mundial de la Salud

# Campus Virtual de Salud Pública

## ARGENTINA

Recursos Educacionales | Argentina | Buscar

### RED Nodos CVSP

CVSP Regional

- BRASIL
- CHILE
- COLOMBIA
- COSTA RICA
- CUBA
- MEXICO
- PERU
- CIESS

### Noticias Red CVSP

- Noticias Cuba: Convocatoria II Taller virtual nacional de ISSS
- Noticias Cuba:

### Bienvenidos al Campus Virtual de Salud Pública de Argentina

Una red para **crear, compartir y colaborar** en los procesos educativos de Salud Pública.


**NOTICIAS**

### Invitación a participar de un WEBINAR

Submitted by adminargentina on Thu, 04/22/2010 - 14:02

Start: 00/00/

Timezone:

### Aprendizaje en Red

- Aula Virtual
- Red REA/OER
- Biblioteca Virtual

### Instituciones

- Ministerio de Salud de la Nación - Dirección Nacional de Capital Humano y Salud Ocupacional
- ESP Buenos Aires
- ESP Córdoba
- ESS-FBCB-UNL
- FLACSO
- Universidad Nacional de la Plata- CUFAR
- Universidad Nacional de la Plata- INUS
- ISALUD

SciELO
Scientific Electronic Library Online

## SciELO Network

About SciELO
Bibliometric Indicators
Access via OAI and RSS
Old Portal SciELO.org

**collections**

Argentina
Brazil
Chile
Colombia
Cuba
Spain
Portugal
Venezuela
Public Health
Social Sciences

**in development**

Bolivia
Costa Rica
Mexico
Paraguay
Peru

## Search article

method: integrated | Entry one or more words | where: Regional | Search

Indexes (Regional): country, author, keyword, title, organization, publication year, document type, original language

## Browse journals

Search by journals

Entry one or more words | pesquisar

By alphabetic list - all

A B C D E F G H I J K L M N O P Q R S T U V Z

By subject - all

Agricultural Sciences
Applied Social Sciences
Biological Sciences
Chemistry
Engineering
Exact and Earth Sciences

## SciELO in numbers

Site usage
Citations
Co-authors

**636** Journals
**16,862** Issues
**254,153** Articles
**5,127,542** Citations

## New

Last Update - 25/apr/2010

**78** Issues

## Services on Demand

User Authentication

e-mail or login:

password:

login

registry | forget my password

## Highligths



## News

# Existing regional networks

BVS
- Países
  - Angola
  - Argentina
  - Barbados
  - Belize
  - Bolívia
  - Brasil
  - Cabo Verde
  - Chile
  - Colômbia
  - Costa Rica
  - Cuba
  - El Salvador
  - Equador
  - Espanha
  - Guatemala
  - Guiné-Bissau
  - Honduras
  - México
  - Moçambique
  - Nicarágua
  - Panamá
  - Paraguai
  - Peru
  - República Dominicana
  - São Tomé e Príncipe
  - Timor Leste
  - Trindade e Tobago
  - Uruguai
  - Venezuela

## Scielo

## VHL / BVS

## Virtual Campi

**RED Nodos CVSP**

CVSP Regional

- BRASIL
- CHILE
- COLOMBIA
- COSTA RICA
- CUBA
- MEXICO
- PERU
- CIESS

**collections**
- Argentina
- Brazil
- Chile
- Colombia
- Cuba
- Spain
- Portugal
- Venezuela
- Public Health
- Social Sciences

**in development**
- Bolivia
- Costa Rica
- Mexico
- Paraguay
- Peru
- South Africa
- Uruguay

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# A regional network of Clinical Trial Registries

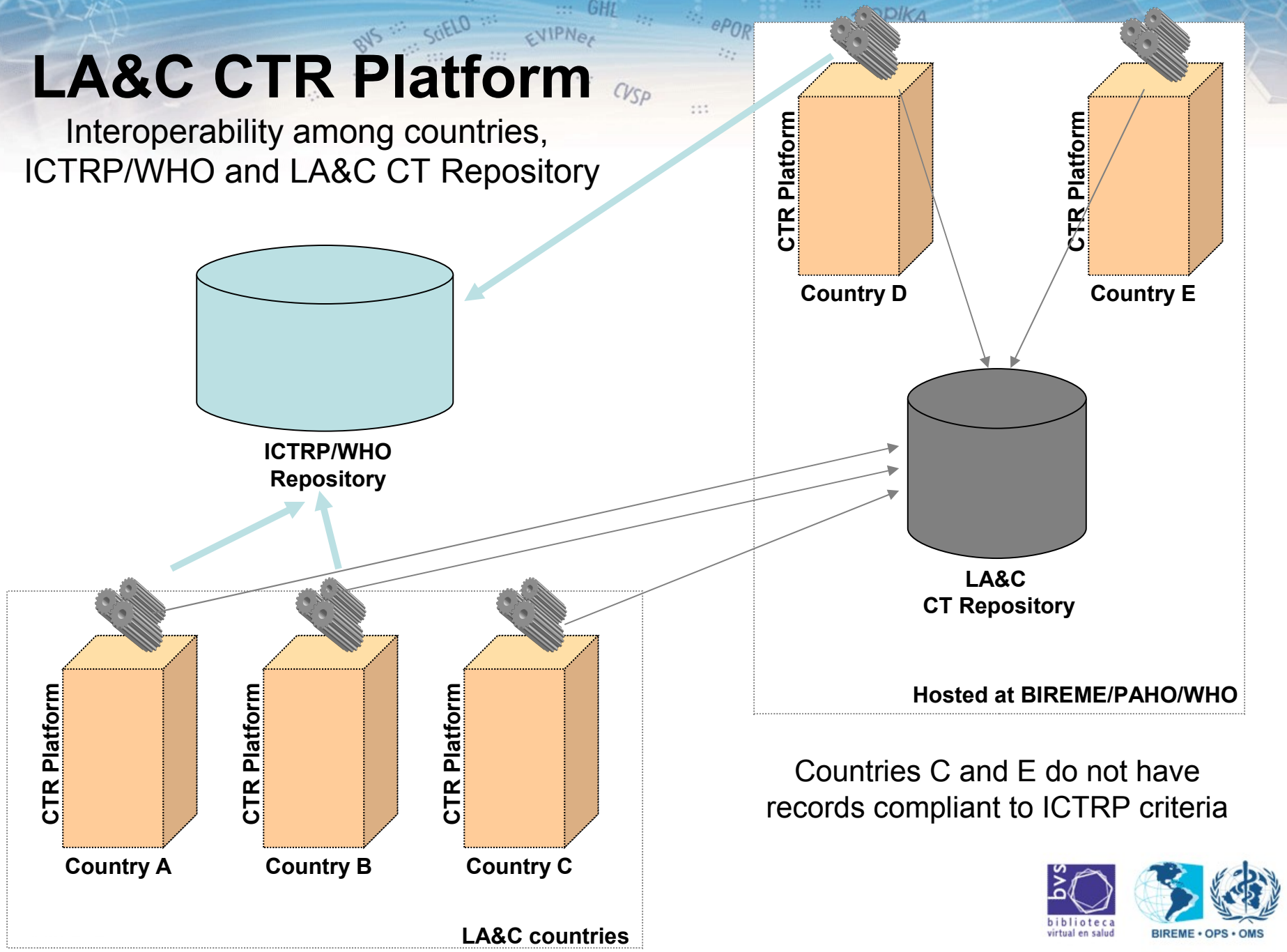
- Following the successful model of VHL, CVSP, Scielo and ScienTI
- Countries may choose to host their own registries, or use our hosting facilities
- Countries may choose to develop their own software, or adapt and use the open platform we are presenting today
- Developing national capabilities to monitor clinical trials

bvs biblioteca virtual en salud

BIREME • OPS • OMS

# LA&C CTR Platform

Interoperability among countries,
ICTRP/WHO and LA&C CT Repository




Countries C and E do not have records compliant to ICTRP criteria

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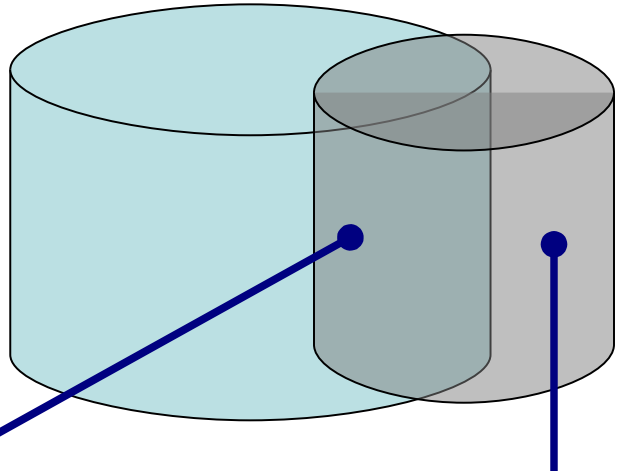
# Distribution of CT records

**ICTRP/WHO Repository**

**LA&C CT Repository**



ICTRP compliant records

other records (eg. non-English)

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# Requirements and compliance with ICTRP standards and best practices

# Clinical Trials Register Platform

## Requirements and specification documents

- DomainReferences: background material for the Clinical Trials application domain
- TrialRegistrationDataSet (TRDS) [ES|PT-BR]: minimum required information for a registered clinical trial
  - Administrative Fields: 1 2 3 4 5 6 7 8 9 10 11
  - Scientific Fields: 12 13 14 15 16 17 18 19 20
- ControlledVocabularies: sources of terms used to describe values in some TRDS fields.
- UserStories: high-level system requirements
  - FiocruzStories, BiremeOpasStories, DecitMsStories, AnvisaStories
- UserRoles: profiles of users of a CTRP instance
- PublishingWorkflow?: life cycle of a trial record
- BestPractices: standards agreed or under discussion by the ICRTP Best Practices Group
- SearchCriteria: criteria for filtering trial records in the advanced search interface
- WorkBreakdown: main modules of the system
- OpenQuestions: answers needed
- Executive Comittee Meetings:
  - 2009: Fiocruz Oct. 2009, Fiocruz Nov. 2009, BIREME Dec. 2009
  - 2010: Elluminate Jan. 2010, BIREME Jan. 2010, Fiocruz Fev. 2010, Elluminate Mar. 20
- Consultative Comittee Meetings: BIREME Jan. 2010, Fiocruz Fev. 2010

project documentation and status:
public and live

## Technical documents

- RegistrationDataModel: mapping of the TRDS to XML elements and RDB entities.
- WebPlatform: analysis and selection of tools for this project
- HowT
- CodingS

**http://reddes.bvsalud.org/projects/clinical-trials**

## WHO International Clinical Trials Registry Platform (ICTRP)

- ICRTP Search Portal
- Main WHO ICRTP Web site
- The Universal Trial Number (UTN)
- WHO Trial Registration Data Set (TRDS)

## ICMJ: International Committee of Medical Journal Editors

- Uniform Requirements for Manuscripts: Obligation to Register Clinical Trials

## ClinicalTrials.gov

- PRS: Protocol Registration System: includes data elements definitions

## Attachments

- Building_a_WHO_Primary_Registry_profile__template__V2.0.pdf (30.8 kB) - added by *renato.murasaki* 9 months ago. "The aim of this form is to help the ICTRP Team to assess whether or not your registry meets the requirements of a WHO Primary Registry. Completing it is the first step in the process of becoming a WHO Primary Registry. For more information on the questions asked on this form please go to the ICTRP web site."
- TRDS_confirmation.pdf (19.0 kB) - added by *renato.murasaki* 9 months ago. "WHO Trial Registration Data Set: Reg ... d display"
- WHO_Primary_Registry_criteria__for_registries__V2.1.pdf (24.7 kB) - added by *renato.murasaki* 9 months ago. "WH ... sion 2.1, April 2009"
- vision-report-0-7-pdf.pdf (238.8 kB) - added by *luciano.ramalho* 8 months ago. "Vision Report: Clinical Trials Registe ... the Caribbean (Version 0.7)"
- ICTRP Data format 1.1 .doc (209.0 kB) - added by *luciano.ramalho* 7 months ago. "ICTRP Data Format 1.1"
- buenaspracticas_espanol.pdf (0.9 MB) - added by *Claudio.NIshizawa* 2 months ago. "Boas Práticas Clínicas - Documento das Américas - espanhol"
- boaspraticas_americas.pdf (0.6 MB) - added by *Claudio.Nishizawa* 2 months ago. "Boas Práticas Clínicas - Documento das Américas - PortuguêsBrasil?"

Edit this page | Attach file

domain references

**http://reddes.bvsalud.org/projects/clinical-trials**

# WHO Trial Registration Data Set

This page in Español | Português

Field numbers, names and descriptions here are taken verbatim from the source: http://www.who.int/ictrp/network/trds/en/index.html

Categorization into administrative and scientific fields done at BIREME to facilitate discussions.

See RegistrationDataModel for a mapping of these fields to actual database fields.

WHO Trial Registration Data Set
- Administrative fields
  - 1. Primary Registry and Trial Identifying Number
  - 2. Date of Registration in Primary Registry
  - 3. Secondary Identifying Numbers
  - 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. Countries of Recruitment
- Scientific fields
  - 12. Health Condition(s) or Problem(s) Studied
  - 13. Intervention(s)
  - 14. Key Inclusion and Exclusion Criteria
  - 15. Study Type
  - 16. Date of First Enrollment
  - 17. Target Sample Size
  - 18. Recruitment Status
  - 19. Primary Outcome(s)

TRDS-20 field descriptions in English

## Administrative fields

### 1. Primary Registry and Trial Identifying Number

Name of Primary Registry, and the unique ID number assigned by the Primary Registry to this trial. (see: PrimaryIdNumber)

### 2. Date of Registration in Primary Registry

Date when trial was officially registered in the Primary Registry. (see: RegistrationDate)

### 3. Secondary Identifying Numbers

Other identifying numbers and issuing authorities besides the Primary Registry, if any. Include the sponsor name and s
number) if available. Also include other trial registries that have issued an identifying number to this trial. There is no lir
numbers that can be provided. (see: SecondaryIdNumbers)

### 4. Source(s) of Monetary or Material Support

Major source(s) of monetary or material support for the trial (e.g., funding agency, foundation, company). (see: SupportSources)

### 5. Primary Sponsor

The individua
for ensuring t
or is responsible

### 6. Secondary Sp

http://reddes.bvsalud.org/projects/clinical-trials

# WHO Trial Registration Data Set

This page in English | Português

Field numbers, names and descriptions here are taken verbatim from the source: http://www.who.int/ictrp/network/trds/en/index.html

Categorization into administrative and scientific fields done at BIREME to facilitate discussions.

See RegistrationDataModel for a mapping of these fields to actual database fields.

WHO Trial Registration Data Set
- Campos administrativos
  - 1. Registro primario y número de identificación del ensayo
  - 2. Fecha de inscripción en el Repositorio Primario
  - 3. Identificadores secundarios del ensayo clínico
  - 4. Fuentes de apoyo monetario o en material
  - 5. Patrocinador principal
  - 6. Patrocinador(es) secundario(s)
  - 7. Contacto para preguntas públicas
  - 8. Contacto para preguntas científicas
  - 9. Título público
  - 10. Título científico
  - 11. Países donde se realiza la selección
- Campos científicos
  - 12. Problemas o situaciones sanitarias estudiadas
  - 13. Intervención(es)
  - 14. Criterios de inclusión y exclusión clave
  - 15. Tipo de ensayo
  - 16. Fecha de la primera inclusión
  - 17. Tamaño previsto de la muestra
  - 18. Estado de reclutamiento
  - 19. Resultados primarios
  - 20

## Campos administrativos

### 1. Registro primario y número de identificación del ensayo

Nombre del Repositorio Primario, y el número de identificación (ID) asignado al ensayo por el Repositorio Primario (vea: PrimaryIdNumber)

### 2. Fecha de inscripción en el Repositorio Primario

Fecha cuando el ensayo fue oficialmente registrado en el Repositorio Primario (vea: RegistrationDate)

### 3. Identificadores secundarios del ensayo clínico

Números de identificación atribuidos por otros organos emisores, ademas del Repositorio Primario, si hay. Incluye el n do al ensayo por el repositorio secundario (por ej. número del protocolo), si disponible. Tambien incluye otros registros de en identificación para este ensayo (p.ex. ClinicalTrials??.gov). No hay límite de cantidade de números de identificación se SecondaryIdNumbers)

### 4. Fuentes de apoyo monetario o en material

Principal o principales fuentes de apoyo financiero o en material para el ensayo. (por ej. agencia de financiación, fundación, empresas) (vea: SupportSources)

### 5. Patrocinador principal

Individuos, o o es
responsable ponsor)

TRDS-20 field descriptions in Spanish

**http://reddes.bvsalud.org/projects/clinical-trials**

# Conjunto de dados de registro de ensaio da OMS

Esta página em English | Español.

Os numeros, nomes e descrições dos campos desta página foram obtidos diretamente da fonte http://www.who.int/ictrp/network/trds/en/index.html

Categorização em campos administrativo e cientifico realizado na BIREME para facilitar as discussões..

Veja RegistrationDataModel para um mapeamento destes campos para os campos correspondentes no banco de dados.

Conjunto de dados de registro de ensaio da OMS
Campos Administrativos
1. Identificador Primário do ensaio clínico no Registro Primario
2. Data de Registro no Registro Primario
3. Identificadores secundários do ensaio clínico
4. Fonte(s) de apoio financeiro ou material
5. Patrocinador Primário
6. Patrocinador(es) Secundário(s)
7. Contato de Relações Públicas
8. Contato para a comunidade científica
9. Título Público
10. Título Científico
11. Paises de Recrutamento
Campos Científicos
12. Condição(ões) ou Problema(s) de saúde estudado(s)
13. Intervenção(ões)
14. Critérios de Inclusão e Exclusão
15. Tipo de Estudo
16. Data da Primeira Inscrição
17. Tamanho da Amostra
18. Situação do recrutamento
19. Desfecho(s) primário(s)
20. De
Campos
21. Si
22. Da
23. In
24. Su
25. Co

TRDS-20 field descriptions in Portuguese

## Campos Administrativos

### 1. Identificador Primário do ensaio clínico no Registro Primario

Nome do Registro Primario e seu identificador primário unico atribuido pelo Registro Primario ao ensaio. (veja: PrimaryIdNumber)

### 2. Data de Registro no Registro Primario

Data em que o ensaio foi oficialmente registrado no Registro Primario. (veja: RegistrationDate)

### 3. Identificadores secundários do ensaio clínico

Outros números de identificação de orgãos emissores, além do Identificador Primário do ensaio clínico, se houver. Incluir o nome do patrocinador e o número de registro de ensaio do patrocinador (p.ex., codigo interno do patrocinador), nome do Comitê de Ética que aprovou o projeto e o número de registro no SISNEP/Plataforma Brasil(numero do CAAE), numero do comunicado especial da ANVISA, numero do UTN, numero
el.
Também incluir outros registros de ensaios que tenham emitido um número de identificação para este ensaio (p.ex. ClinicalTrials?.gov). Não há limite para a quantidade de números de identificação secundários que podem ser fornecidos. (veja: SecondaryIdNumbers)

### 4. Fonte(s) de apoio financeiro ou material

Principal(is) f

### 5. Patrocinado

**http://reddes.bvsalud.org/projects/clinical-trials**

# Field 12. Health Condition(s) or Problem(s) Studied

Field 12. Health Condition(s) or Problem(s) Studied
- WHO description
- Schema
- Validation
- Labels
- Sample Values
- Discussion

## WHO description

Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented. If the study is conducted in healthy human volunteers not belonging to the target population (e.g., a preliminary safety study), an appropriate keyword will be defined for users to select.

## Schema

PT: 3 opcoes de campos:

12a) texto livre - recomendar utilizar o UMLS

12b) codigo - utilizar o 1o nivel de doencas do DeCS ou capitulos do CID10

12c) palavra chave - utilizar nivel mais detalhado do DeCS ou do CID10

Exibir no formulario o 12b primeiro, depois o 12c e por ultimo o 12a.

## Validation

At least one of each subfield (12a,12b,12c) is required

## Labels

EN: Health Condition(s) or Problem(s) Studied

PT: Condição(ões) ou Problema(s) de saúde estudado(s)

ES:

## Sample Values

sample 1

search for linfoma MALT UMLS 0.43 CID-10 C85.9

C85.9 Linfoma não-Hodgkin de tipo não especificado

discussion page for one of the TRDS fields

# Controlled Vocabularies

This page documents sources of terms that may be used to describe values in some of the TRDS fields.

Please note the criteria for use of any controlled vocabulary in REBRAC.

HealthConditionsField (12) vocabularies
- DeCS (MeSH translation with extensions)
- CID-10 (ICD-10 translation)
- ICF (CIF)

InterventionsField (13) vocabularies
- DCI (INN translation)
- DCB
- Farmacopéia Homeopática Brasileira
- ATC/DDD
- Fitoterápicos

Other controlled vocabularies
Criteria for use in REBRAC

## HealthConditionsField (12) vocabularies

### DeCS (MeSH translation with extensions)

**used in subfields**: HealthConditionsField (12b, 12c)

**how to obtain**: BIREME will provide a web service to allow users to pick descriptors.

**online sources**

- EN, ES, PT: http://decs.bvs.br/homepage.htm

### CID-10 (ICD-10 translation)

**used in subfields**: HealthConditionsField (12b, 12c)

**how to obtain**: BIREME will ask WHO about this

**online sources**

- EN: http://apps.who.int/classifications/apps/icd/icd10online/

### ICF (CIF)

**used in subfields**: HealthConditionsField (12b, 12c)

**how to obtain**: BIREME will ask WHO about this

**online sources**

- EN, ES: http://apps.who.int/classifications/icfbrowser/
- PT: (Centro de Classificação de Doenças da USP tem a versão m portugês da CIF. Laguardia enviou mensagem...)

dicussion page for controlled vocabularies

# Best Practices

## Agreed

Best Practices
Agreed
Accepting data from partner information systems
Audit trails
Authenticity of the registrant
Authenticity of the trial
Data standard: Countries of recruitment
Data standard: Secondary Identifiers
Prospective translation of the TRDS
Provisional registration
Retrospective registration of trials
Unique trial registration
Validity: Is the information registered correct and complete?
Draft

### Accepting data from partner information systems

Summary:

- Primary or ICMJE-approved registries should be prepared to develop mechanisms for accepting data from Partner Registries or other appropriate data providers.
- Primary or ICMJE-approved registries that accept data from Partner Registries or other appropriate data providers must ensure that these data meet the WHO criteria for data content, quality and validity before being incorporated into the Primary Registry database.

Details and discussion: DataFromPartners

### Audit trails

Summary:

- Significant changes that must be included in audit trails are changes that alter the meaning of text in a data item.
- Registries may need, for legal reasons such as data privacy laws, to make significant changes to some fields and to suppress the original information. In such cases the audit trail should indicate that the change was made and when, but should state that the original information is no longer being displayed for legal reasons and that the original information is held on file by the registry.

Details and discussion: AuditTrails?

### Authenticity of the registrant

Summary:

- Registries must contact and receive replies from the person submitting the registration request using details cited in trial … will be an appropriate contact.
- When possible, registries should obtain institutional contact details

Details and discussion: RegistrantAuthenticity?

### Authenticity of the trial

ICTRP best practices summary

# How the regional platform is being developed

# Think regional, act national

- Brazilian National Clinical Trials Registry
  - EnsaiosClinicos.gov.br
  - Currently at http://ec.beta.bvsalud.org
  - primary registry but restricted to trials in Brazil
- Team
  - BIREME, MS, Fiocruz, Anvisa, PAHO office
- Funding
  - 50% PAHO
  - 50% Ministério da Saúde do Brasil and Fiocruz

## Estórias de usuários fornecidas pela Decit / Ministério da Saúde

Como um
Registrador
Eu quero
importar os dados já registrados na Plataforma Brasil segundo um padrão XML definido
Para que
eu possa economizar tempo no registro de ensaio clínico no Rebrac

---

Como um
Revisor
Eu quero
garantir que um ensaio só seja considerado completo para fins de ganhar um numero REBRAC quando as informações já estiverem inseridas nos 2 idiomas (portugues e ingles) quando o estudo for brasileiro
Para que
eu possa garantir a compatibilidade com os padrões da OMS.

---

Como um
Administrador
Eu quero
garantir que o sistema utilize todos os padrões internacionais de dados disponíveis
Para que
eu possa minimizar o esforço de integração e compatibilidade futura.

---

As a
Administrator
I want to
send automatically to each researcher an warning message about deadlines, for example 15 days or 1 week before.
so that
this wi

As a
Pesquis

user stories contributed by:

- Fiocruz
- Ministério da Saúde
- ANVISA
- BIREME

**http://reddes.bvsalud.org/projects/clinical-trials**

# User Roles in a CTR instance

Trialist
: person responsible for registering a clinical trial

Reviewer
: person responsible for approving the record and changes of a Clinical Trial.

Administrator
: system administrator responsible for managing the CTR instance

Citizen
: a member of the general public

---

## Comments

Anvisa
: person responsible for the regulatory approval of a clinical trial.

As mentioned in the initial meeting of the Executive Committee, "Anvisa" is not a good name for a role. A role must describe a person, not an institution, because only real people interact with the system, institutions do not interact with it.

Also, everyone present at that meeting agreed that we needed the roles "Trialist", "Reviewer", "Administrator" [illegible] first step is to find a name that describes a person, and not an institution. (LR)

Edit this page | Attach file | Delete this version | Delete page

**Download in other formats:**
Plain Text

defined user roles:
- trialist
- reviewer
- administrator
- citizen (public)

# Work Breakdown

Main modules of the BIREME Clincial Trials Platform

See PrioritizedFeatures for these items ordered by priority.

Work Breakdown
- Trialist personal data management
- Trialist trial record submission
- Reviewer trial record revision
- Citizen public interface
- Administrator operations management
- Quality assurance
- Documentation

## Trialist personal data management

- signup: create account
- login
- trialist dashboard (lists: submissions, pending issues)
- change password
- reset password
- set preferred language

## Trialist trial record submission

- list own clinical trial submissions
- start submission and determine mandatory registration languages
- submission status overview
- edit clinical trial record in each language
- upload submission attachments
- view and handle pending issues
- request support
- upload trial record in ICTRP XML format

## Reviewer trial record revision

- login

work breakdown structure: what needs to be built

# Priotized Feadures

Main modules of the BIREME Clincial Trials Platform

Priotized Feadures
Priority 1: required for Alpha 1
Priority 2: required for Alpha 2
Priority 3: required for Beta 1
Priority 4: required Beta 2

## Priority 1: required for Alpha 1

- Trialist login
- Trialist start submission and determine mandatory registration languages
- Trialist edit clinical trial record in each language
- Trialist upload submission attachments and mark as public or confidential
- Trialist submission status overview
- Trialist list own clinical trial submissions
- Trialist upload trial record in XML format
- Trialist signup: create account
- Trialist change password
- Reviewer login
- Reviewer review submission and post issues at field and record level
- Reviewer approve translation
- Reviewer review submission attachments
- Administrator edit UI translation (Rosetta system)
- Administrator edit field-level help: help text displayed besides each field
- Administrator edit FAQ
- Administrator edit controlled vocabularies
- Administrator manage reviewer accounts
- Administrator export XML to ICTRP

prioritized work breakdown structure: what needs to be built and when

# RedDes

Red de Desarrolladores de las Redes BVS, SciELO y ScienTI

biblioteca virtual em saúde

Search

logged in as luciano.ramalho | Logout | Preferences

Home | Timeline | Roadmap | Browse Source | View Tickets | New Ticket | Downloads | Admin

Available Reports | Custom Query

## {1} Active Tickets (44 matches)

- List all active tickets by priority.
- Color each row based on priority.

Edit report | Copy report | Delete report

| P.name | Ticket | Summary | Component | Version | Milestone | Type | Owner | Status | Created |
|---|---|---|---|---|---|---|---|---|---|
| 1 | #23 | Trialist edit clinical trial record in each language | Trialist | None | alpha1 | task | | new | 04/05/10 |
| 1 | #26 | Trialist: list own clinical trial submissions | Trialist | None | alpha1 | task | | new | 04/05/10 |
| 1 | #31 | Review submission and post issues at field and record level | Reviewer | None | alpha1 | task | | new | 04/05/10 |
| 2 | #22 | Start submission and determine mandatory registration languages | Trialist | None | alpha1 | task | | new | 04/05/10 |
| 2 | #25 | Trialist submission status overview | Trialist | None | alpha1 | task | | new | 04/05/10 |
| 2 | #40 | Export XML to ICTRP | Administrator | None | alpha1 | task | | new | 04/05/10 |
| 2 | #51 | Spanish translation of the UI | All Users | None | beta1 | task | | new | 04/05/10 |
| 3 | #27 | Trialist upload trial record in XML format | Trialist | None | alpha1 | | | | |
| 3 | #29 | Trialist: change own password | Trialist | None | alpha1 | | | | |
| 3 | #30 | Reviewer login | Reviewer | None | alpha1 | | | | |
| 3 | #32 | Approve translation | Reviewer | None | alpha1 | | | | |
| 3 | #33 | Review submission attachments | Reviewer | None | alpha1 | | | | |
| 3 | #37 | Edit FAQ | Administrator | None | alpha1 | | | | |
| 3 | #39 | Manage reviewer accounts | Administrator | None | alpha1 | | | | |
| 3 | #41 | Basic public search | All Users | None | alpha1 | | | | |
| 3 | #42 | Public view of detailed clinical trial record | All Users | None | alpha1 | | | | |
| 3 | #43 | Public view of FAQ | All Users | None | alpha1 | | | | |
| 3 | #44 | Trialist dashboard | Trialist | None | alpha2 | | | | |
| 3 | #45 | Trialist: view and handle pending issues | Trialist | None | alpha2 | | | | |
| 3 | #46 | Trialist: request support | Trialist | None | alpha2 | | | | |
| 3 | #47 | Reviewer dashboard | Trialist | None | alpha2 | | | | |
| 3 | #48 | Administrator: assign trials and issues to reviewers | Administrator | None | beta1 | | | | |
| 3 | #49 | Administrator: view workflow reports | Administrator | None | beta1 | task | | new | 04/05/10 |

development tracking:
each ticket is a feature do be implemented or a bug to be fixed


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## Roadmap

Show already completed milestones

Update

### Milestone: alpha1

*4 weeks* late (03/25/10)

30%

Closed tickets: 7 Active tickets: 16 / Total tickets: 23

### Milestone: alpha2

*2 days* late (04/20/10)

0%

Closed tickets: 0 Active tickets: 5 / Total tickets: 5

### Milestone: beta1

Due in 4 weeks (05/17/10)

8%

Closed tickets: 1 Active tickets: 12 / Total tickets: 13

### Milestone: beta2

Due in 8 weeks (06/15/10)

21%

Closed tickets: 3 Active tickets: 11 / Total tickets: 14

roadmap shows progress for each milestone

Add new milestone


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← Previous Period | Next Period →

## Timeline

View changes from 04/22/10
and 30 days back.
- [x] Ticket changes
- [x] Repository checkins
- [x] Milestones
- [x] Wiki changes

Update

### 04/22/10: Today

10:36 FiocruzStories edited by luciano.ramalho
(diff)

### 04/20/10:

17:53 Changeset [298] by luciano.ramalho
added backup script; removed empty models.py from decsclient app

17:22 Changeset [297] by fabio.montefuscolo
fix partially the id for cluetip

### 04/19/10:

17:47 Changeset [296] by fabio.montefuscolo
unecessary line causes 404 error

17:23 Changeset [295] by fabio.montefuscolo
Delete the big version of 'cluetip'

17:22 Changeset [294] by fabio.montefuscolo
Provide a cool tooltip that enhance and complete #71

16:07 Changeset [293] by luciano.ramalho
updated form for help text inclusion

11:21 Changeset [292] by fabio.montefuscolo
Close script tag to avoid html parsing corruption.

10:14 Ticket #69 (change style for button "Submit a new trial") closed by fabio.montefuscolo
implemented

### 04/16/10:

timeline shows changes to documentation and code in real time

# Changeset 297

**Timestamp:** 04/20/10 17:22:18 (41 hours ago)
**Author:** fabio.montefuscolo

**Message:** fix partially the id for cluetip

**Location:** trunk/clinicaltrials
**Files:** 2 modified

- repository/trds_forms.py (2 diffs)
- static/js/submission.utils.js (1 diff)

View differences: inline
Show 2 lines around each change
Ignore:

changes are displayed down to each line of code

Unmodified | Added | Removed

## trunk/clinicaltrials/repository/trds_forms.py

| r294 | r297 | |
|---|---|---|
| 58 | 58 | 'field': unicode(bf), |
| 59 | 59 | 'help_text': help_text, |
| 60 | | 'help_id': 'help%s' % help_record.pk, |
| | 60 | 'help_id': 'id_%s-help%s' % ((self.prefix or name),help_record.pk), |
| 61 | 61 | 'issue': issue_text,}) |
| 62 | 62 | if top_errors: |
| ... | ... | |
| 77 | 77 | 'field': '', |
| 78 | 78 | 'help_text': '', |
| 79 | | 'help_id': 'help%s' % help_record.pk, |
| | 79 | 'help_id': 'id_%s-help%s' % (self.prefix,help_record.pk), |
| 80 | 80 | 'issue': '',} |
| 81 | 81 | output.append(last_row) |

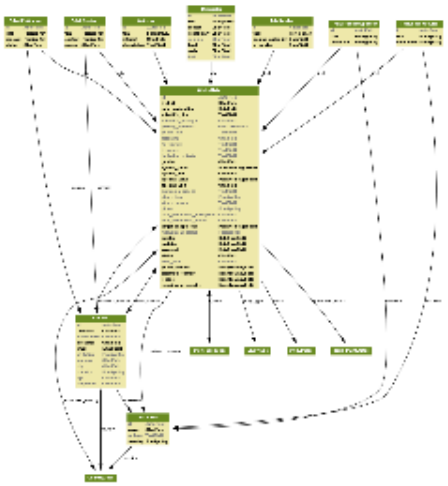
## trunk/clinicaltrials/static/js/submission.utils.js

Tabular | Unified

| r291 | r297 | |
|---|---|---|
| 15 | 15 | var newFor = $(this).attr('for').replace('-' + (total-1) + '-','-' + total + '-'); |

# Registration Data Model

Mapping of the 20 TRDS fields to XML elements and database entities.



Registration Data Model
Administrative fields
Scientific fields
Adittional required fields
Additional fields

data model: mapping of ICTRP XML fields to a relational database schema

## Administrative fields

| TRDS | wiki name | XML element | repeat | max.len. | model class | attribut | | search |
|---|---|---|---|---|---|---|---|---|
| 1 | PrimaryIdNumberField | trial_id | N | 255 | ClinicalTrial | trial_id | ) | basic * |
| 2 | RegistrationDateField | date_registration | N | 10 | ClinicalTrial | date_re | | adv. |
| 3a | SecondaryIdNumbersField | issuing_authority | Y | 255 | TrialNumber | trial_nu | ber set | |
| 3b | | secondary_id | Y | 50 | | | | basic |
| 4 | SupportSourcesField | source_name | Y | 1000 | Institution | source_name_set | ← Institution set (2) | basic (name only) |
| 5 | PrimarySponsorField | primary_sponsor | N | 2000 | ClinicalTrial | primary_sponsor | ForeignKey(Institution) | basic (name only) |
| | | | | | | | | basic |

## Administrative fields

| TRDS | wiki name | XML element | repeat | max.len. | model class | attribute name | type | search |
|---|---|---|---|---|---|---|---|---|
| 1 | PrimaryIdNumberField | trial_id | N | 255 | ClinicalTrial | trial_id | Char(255) (1) | basic * |
| 2 | RegistrationDateField | date_registration | N | 10 | ClinicalTrial | date_registration | Date | adv. |
| 3a | SecondaryIdNumbersField | issuing_authority | Y | 255 | TrialNumber | trial_number_set | ← TrialNumber set (2)) | |
| 3b | | secondary_id | Y | 50 | | | | basic |
| 4 | SupportSourcesField | source_name | Y | 1000 | Institution | source_name_set | ← Institution set (2) | basic (name only) |
| 5 | PrimarySponsorField | primary_sponsor | N | 2000 | ClinicalTrial | primary_sponsor | ForeignKey(Institution) | basic (name only) |
| 6 | SecondarySponsorsField | sponsor_name | Y | 2000 | Institution | secondary_sponsor_set | ← Institution set (2) | basic (name only) |
| 7 | PublicContactField | contact type="public" (3) | Y | 1370 (4) | Contact | public_ | et (2) | basic (city) adv. (name only) |
| | | contact type="site" (3) | Y | 1370 (4) | Contact | site_co | et (2) | basic (city) |
| 8 | ScientificContactField | contact type="scientific" (3) | Y | 1370 (4) | Contact | scientif | et (2) | adv. (name only) |
| 9a | PublicTitleField | public_title | N | 2000 | ClinicalTrial | public_ | | basic * |
| 9b | | acronym | N | 255 | ClinicalTrial | acronyr | | basic |
| | | acronym_expansion | N | 255 | ClinicalTrial | acronyr | | basic |
| 10a | ScientificTitleField | scientific_title | N | 2000 | ClinicalTrial | scientif | | basic |
| 10b | | scientific_acronym | N | 255 | ClinicalTrial | scientif | | basic |
| | | scientific_acronym_expansion | N | 255 | ClinicalTrial | scientif | | basic |
| 11 | RecruitmentCountriesField | country2 | Y | 50 | RecruitmentCountry | recruitme | Country set (2) | basic |

data model: mapping of ICTRP XML fields to a relational database schema

## Scientific fields

| TRDS | wiki name | XML element | repeat | max.len. | model class | attribute name | type | |
|---|---|---|---|---|---|---|---|---|
| 12a | HealthConditionsField | hc_freetext | N | 8000 | ClinicalTrial | hc_freetext | Char(8000) | basic |
| 12b | | hc_code | Y | 255 | ConditionTag | hc_category_set | ← ConditionTag set | basic |

## Scientific fields

| TRDS | wiki name | XML element | repeat | max.len. | model class | attribute name | type | |
|---|---|---|---|---|---|---|---|---|
| 12a | HealthConditionsField | hc_freetext | N | 8000 | ClinicalTrial | hc_freetext | Char(8000) | basic |
| 12b | | hc_code | Y | 255 | ConditionTag | hc_category_set | ← ConditionTag set (2) | basic |
| 12c | | hc_keyword | Y | 255 | ConditionTag | hc_keyword_set | ← ConditionTag set (2) | basic |
| 13a | InterventionsField | i_freetext | N | 8000 | ClinicalTrial | i_freetext | Char(8000) | basic |
| 13b | | i_code | Y | 255 | InterventionTag | i_category_set | ← InterventionTag set (2) | basic |
| 13c | | i_keyword | Y | 255 | InterventionTag | i_keyword_set | ← InterventionTag set (2) | basic |
| 14a | InclusionCriteriaField | inclusion_criteria | N | 8000 | ClinicalTrial | inclusion_criteria | Char(8000) | basic |
| 14b | | gender | N | 50 | ClinicalTrial | gender | Char(50) | adv. |
| 14c | | agemin | N | 50 | ClinicalTrial | agemin_value | PositiveInteger | adv. |
| | | | | | ClinicalTrial | agemin_unit | Char(1) | adv. |
| 14d | | agemax | N | 50 | ClinicalTrial | agemax_value | | |
| | | | | | ClinicalTrial | agemin_un | | |
| 14e | | exclusion_criteria | N | 8000 | ClinicalTrial | exclusion_criteria | | |
| 15a | StudyTypeField | study_type | N | 255 | ClinicalTrial | study_type | | |
| 15b | | study_design | N | 1000 | ClinicalTrial | study_design | | |
| 15c | | phase | N | 255 | ClinicalTrial | phase | | |
| 16a | FirstEnrollmentDateField | type_enrollment | Y (5) | 50 | | | | |
| 16b | | date_enrollment | Y (5) | 10 | ClinicalTrial | date_enrollment_antici | | |
| | | | | | ClinicalTrial | date_enrollment_actua | | |
| 17 | SampleSizeField | target_size | N | 255 | ClinicalTrial | target_sample_size | | |
| 18 | RecruitmentStatusField | recruitment_status | N | 255 | ClinicalTrial | recruitment_status | | (currently ing) * |
| 19 | PrimaryOutcomesField | primary_outcome | Y | 8000 | Outcome | primary_outcome_set | | |
| 20 | SecondaryOutcomesField | secondary_outcome | Y | 8000 | Outcome | secondary_outcome_s | | |

(*) fields to show in the basic search result. Other fields to show: updating_date

data model: mapping of ICTRP XML fields to a relational database schema

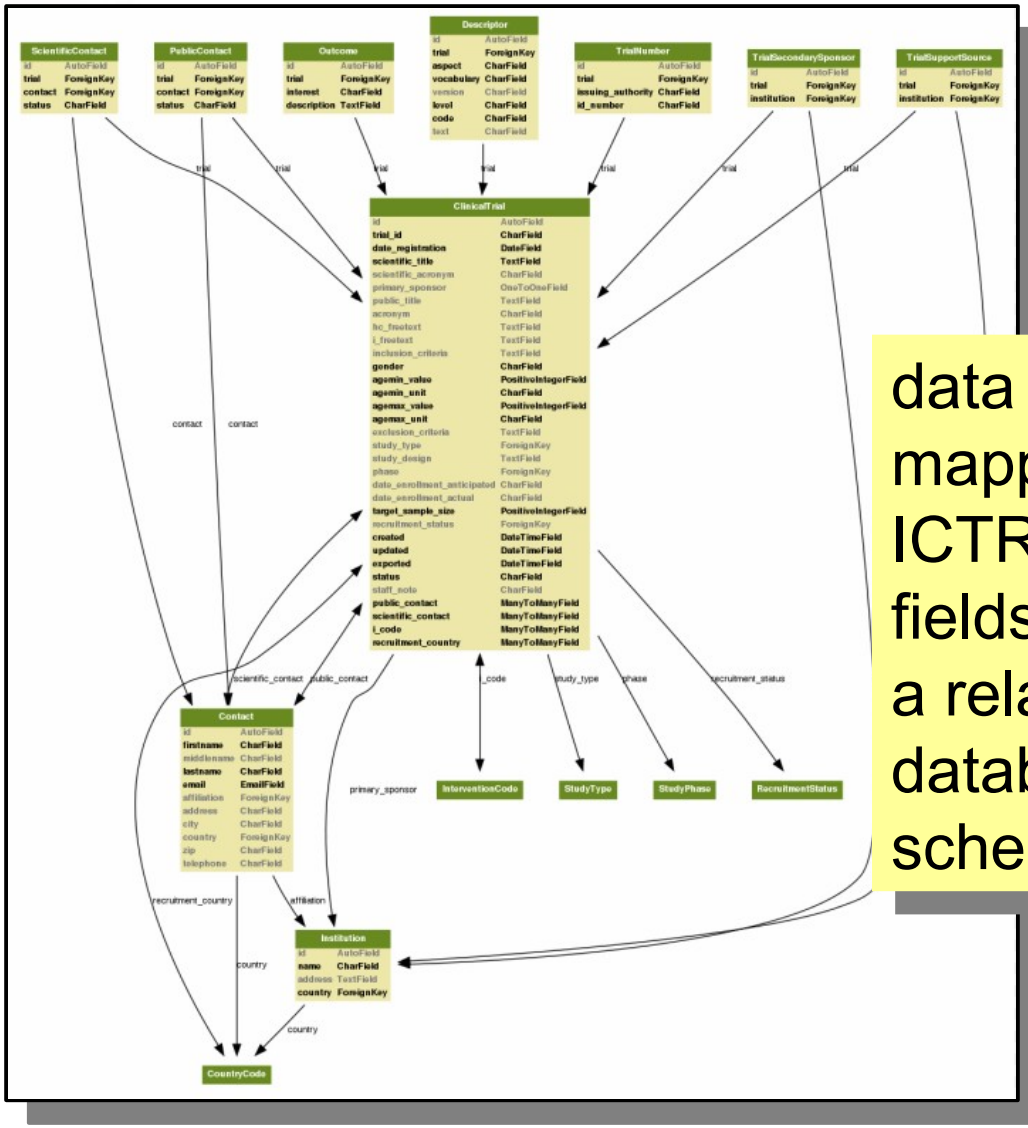
## Adittional required fields

| ICTRP-DF | name | XML element | repeat | max.len. | model class | attribute name | type |
|---|---|---|---|---|---|---|---|
| A1 | URL | url | N | 255 | ClinicalTrial | canonical_url | ClinicalTrial method (7) |

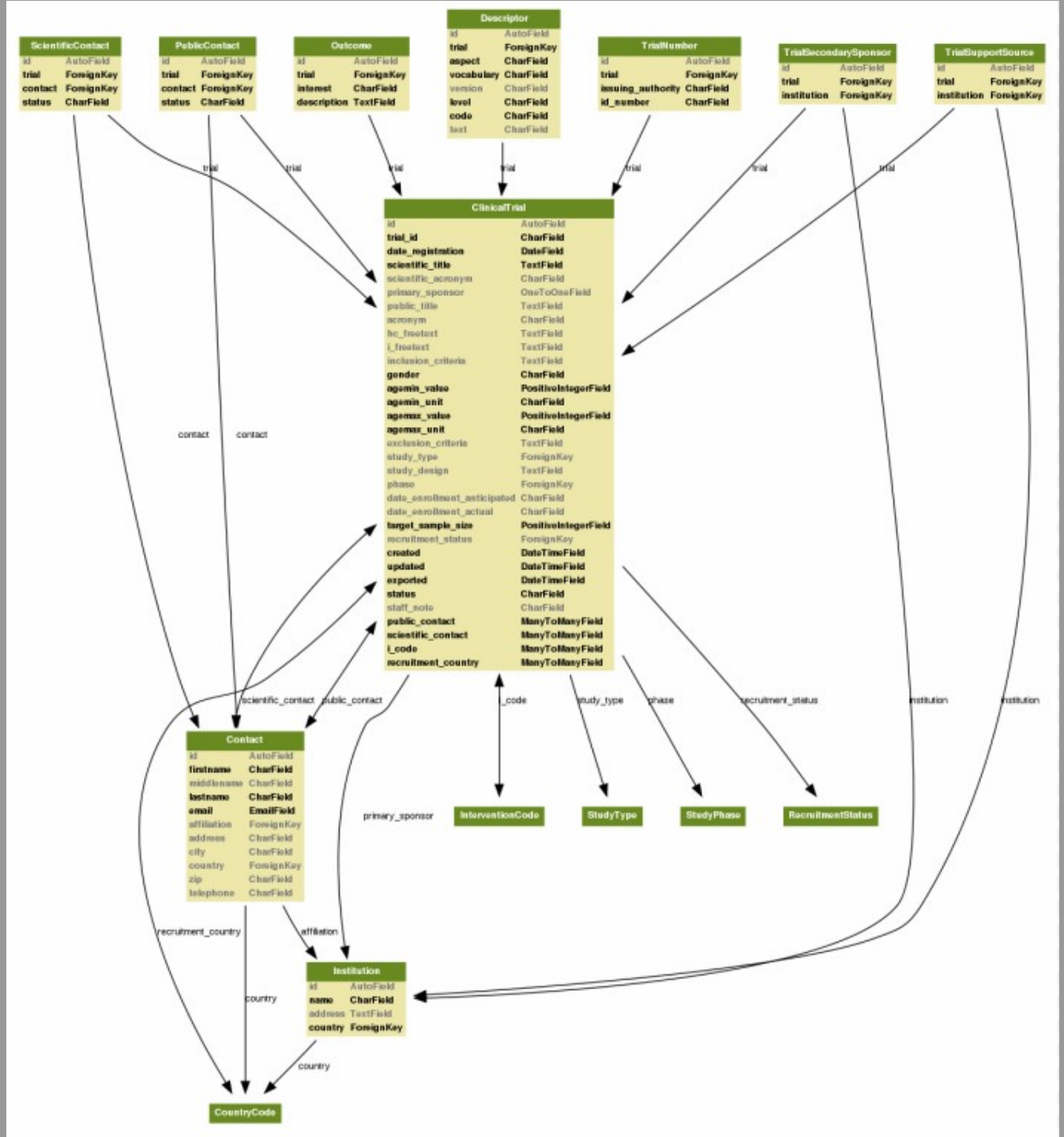
(1) The maxi

**http://reddes.bvsalud.org/projects/clinical-trials**

# A relational, SQL database




data model: mapping of ICTRP XML fields to a relational database schema


ScientificContact
id AutoField
trial ForeignKey
contact ForeignKey
status CharField
PublicContact
id AutoField
trial ForeignKey
contact ForeignKey
status CharField
Outcome
id AutoField
trial ForeignKey
interest CharField
description TextField
Descriptor
id AutoField
trial ForeignKey
aspect CharField
vocabulary CharField
version CharField
level CharField
code CharField
text CharField
TrialNumber
id AutoField
trial ForeignKey
issuing_authority CharField
id_number CharField
TrialSecondarySponsor
id AutoField
trial ForeignKey
institution ForeignKey
TrialSupportSource
id AutoField
trial ForeignKey
institution ForeignKey
trial
ClinicalTrial
id AutoField
trial_id CharField
date_registration DateField
scientific_title TextField
scientific_acronym CharField
primary_sponsor OneToOneField
public_title TextField
acronym CharField
hc_freetext TextField
i_freetext TextField
inclusion_criteria TextField
gender CharField
agemin_value PositiveIntegerField
agemin_unit CharField
agemax_value PositiveIntegerField
agemax_unit CharField
exclusion_criteria TextField
study_type ForeignKey
study_design TextField
phase ForeignKey
date_enrollment_anticipated CharField
date_enrollment_actual CharField
target_sample_size PositiveIntegerField
recruitment_status ForeignKey
created DateTimeField
updated DateTimeField
exported DateTimeField
status CharField
staff_note CharField
public_contact ManyToManyField
scientific_contact ManyToManyField
i_code ManyToManyField
recruitment_country ManyToManyField
contact
scientific_contact
public_contact
i_code
study_type
phase
recruitment_status
institution
Contact
id AutoField
firstname CharField
middlename CharField
lastname CharField
email EmailField
affiliation ForeignKey
address CharField
city CharField
country ForeignKey
zip CharField
telephone CharField
primary_sponsor
InterventionCode
StudyType
StudyPhase
RecruitmentStatus
recruitment_country
affiliation
Institution
id AutoField
name CharField
address TextField
country ForeignKey
country
CountryCode

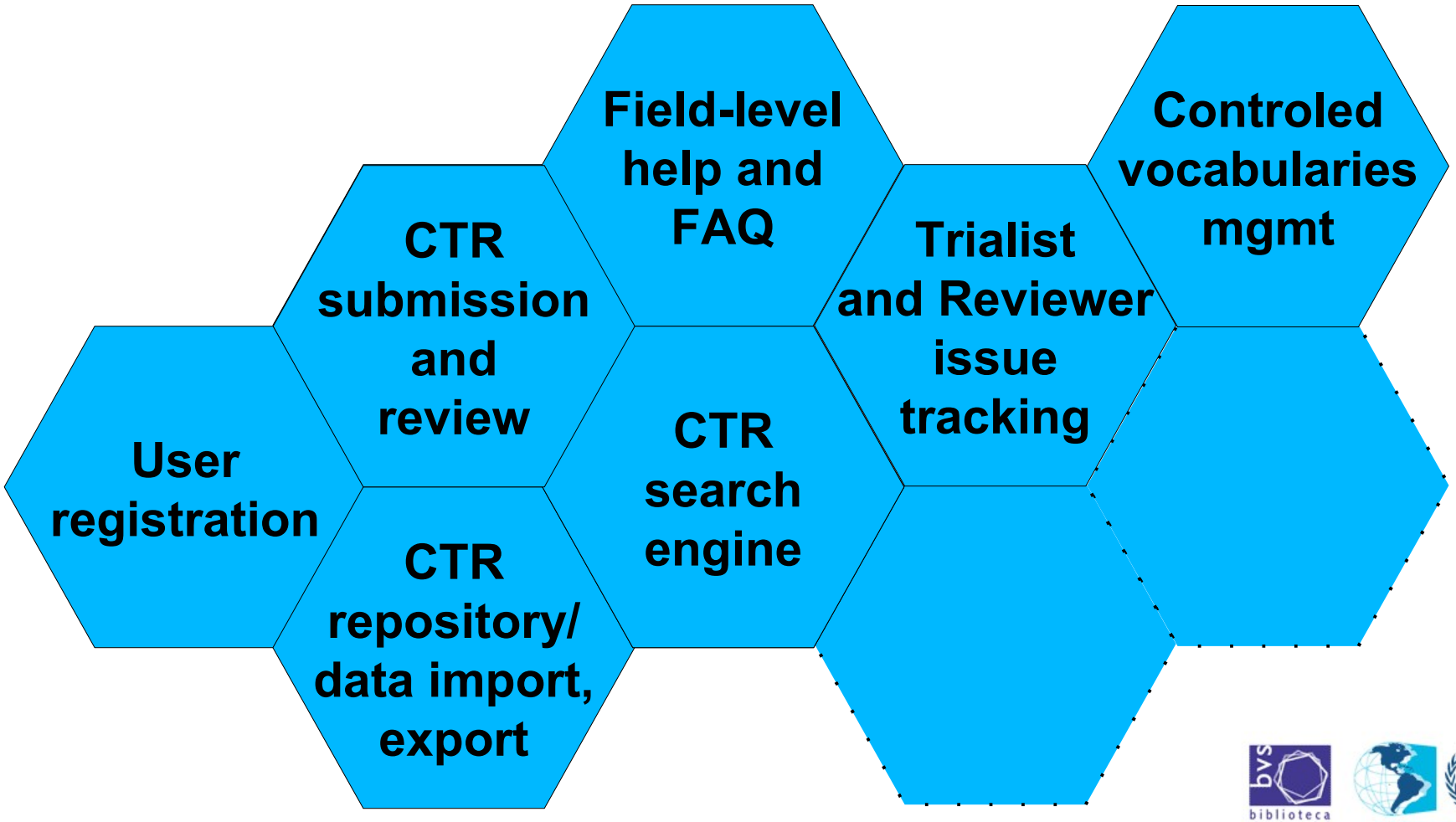
# Software foundations

- Written in Python, a modern, easy to learn programming language
  - used by Google, RedHat, Novell, MIT etc.
- Leverages Django, a modern, easy to learn web development toolkit
  - used by Washington Post, Tabblo, Focus.com etc.
- Relational database storage
  - compatible with Oracle, PosgreSQL and MySQL

# Software features

- Multi-lingual
  - user interface and content can be translated to any language or set of languages
  - CT registry operators can edit help text, vocabularies etc. at any time
- Multi-platform
  - runs on any modern computer (Windows, MacOSX, Linux, FreeBSD...)
- Modular
  - functionality is split into reusable modules

# Software modules



# Fields which need translation

1. Primary Registry and Trial Identifying Number
2. Date of Registration in Primary Registry
3. Secondary Identifying Numbers
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**

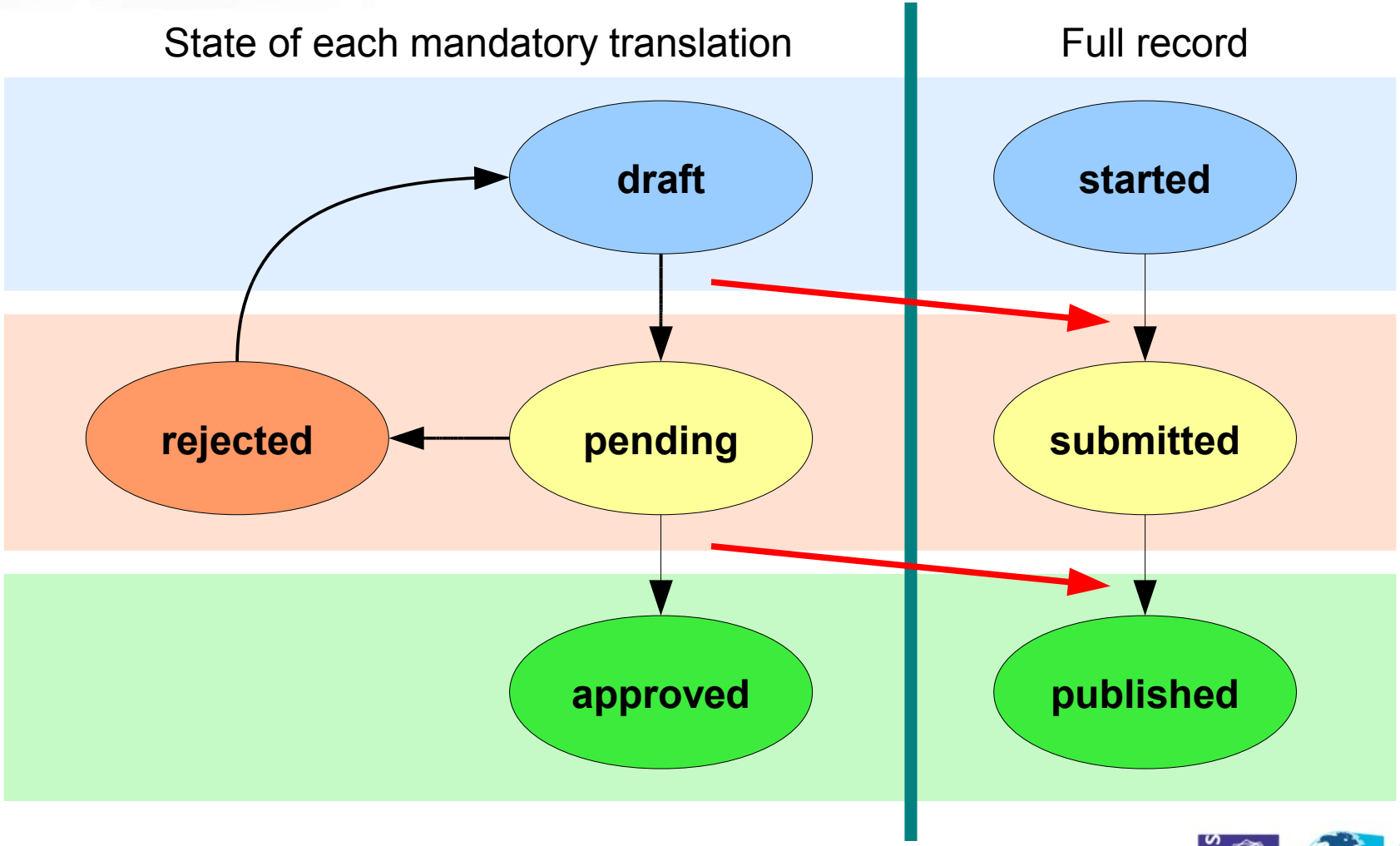
only 8 fields
out of 20 need
translation

# Fields which need translation

11. Countries of Recruitment
12. **Health Condition(s) or Problem(s) Studied**
13. **Intervention(s)**
14. **Key Inclusion and Exclusion Criteria**
15. **Study Type**
16. Date of First Enrollment
17. Target Sample Size
18. Recruitment Status
19. **Primary Outcome(s)**
20. **Key Secondary Outcome(s)**

only 8 fields out of 20 need translation

# Workflow: publishing process



# What is Open Source Software

- Open Source Software is[1]
  - Software licensed with a copyright licensecompliant with the Open Source Definition (OSD)
  - Software is distributed with its source code in a human readable format
  - Software is developed in an open and collaborative way by groups of developers

[1] Quoted from “Learn About Open Source”, a presentation by Alolita Sharma of the Open Source Initiative http://www.opensource.org/osi-open-source-education

# A key point: the “fishbowl”

“Software developed in an open and collaborative way by groups of developers"

- It is not enough to freely distribute the software and put the source code in an open repository
- Strategic and tactical decisions must be made in an open way, allowing and encouraging participation
  - Usually, via a public mailing list and meetings open to all interested parties

# Sustainable development

- Participation fosters an active community
- An active community provides:
  - Better, more qualified feedback
  - Content contributions in the form of documentation, presentations, best practices, translations etc.
  - Software contributions in the form of bug fixes, patches, add-ons and core enhancements
- This leads to sustainable software development

# Designed for Wide Deployment

- Multi-lingual user interface, help system and repository
- Multi-platform language and toolkit
- Mainstream database technology
- Technical documentation in English
- Source code in English
- Standard Open Source procedures and best practices

# Thank you

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