EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Clinical Trials Register (EU-CTR V1.1)

Noémie Manent
Compliance and Inspection Sector

Agenda

- EU Clinical Trial Register (EU CTR)
- WHO International Clinical Trials Registry Platform (ICTRP)
- Demo

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Clinical Trial Register (EU CTR)

EU Clinical Trials Register

Launched on 22nd March 2011

It contains Protocol related data on:

- Clinical trials starting from 01.05.2004
- Phase II/III/IV Adult Clinical Trials with at least 1 site in the EU/EEA
- All phases paediatric Clinical Trials conducted in EEA
- Paediatric clinical trials that are conducted completed outside of the EEA if they are part of an agreed Paediatric Investigational Plan (PIP) (including a small % of adult phase I trials if they are part of a PIP)

What is not currently included in the register?

- Results of the clinical trials
- Non-interventional clinical trials
- Information on clinical trials for surgical procedures, medical devices or psychotherapeutic procedures
- Process of joining a clinical trial
- Provide navigation in languages other than English (translation of the webpage in all EU languages will be available in April 2012)

Transparency : legal requirements

For the protocol related information and for the results related information

Two Regulations

- Article 57(2) of Regulation (EC) No 726/2004
  - Complements the directive on clinical trial 2001/20/EC that establishes the database from which the data can be published into the regsiter (data fields)
- Articles 41 & 53 of Regulation (EC) No 1901/2006 “paediatric regulation”
  - Relates to CT carried out in 3rd country and contained in an agreed paediatric investigation plan (PIP)
  - Make public part of the information on paediatric clinical trials

Criteria for publication of Clinical Trials:

CTs in adults	CTs in paediatric population
•positive NCA decision •positive IEC opinion and related dates appearing in EudraCT	•positive NCA decision •IEC opinion can be either positive or negative and related dates will also appear

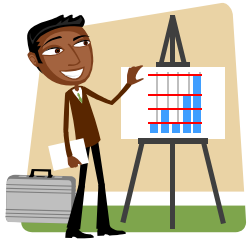
EudraCT Number	Resubmission Letter	Regulatory Authority	Version	CA Decision	CA Decision Date	IEC Opinion	IEC Opinion Date	Options
2008-002340-42	First Submission	Spain - AEMPS	1	Authorised	2008-09-10	Favourable	2008-08-01	Reviews IoCs Amendments
2008-005120-86	First Submission	Spain - AEMPS	1	Authorised	2008-12-18	Favourable	2008-12-05	Reviews IoCs Amendments
2008-002283-34	First Submission	Belgium - FPS Health-DGM	2	Authorised	2008-05-28			Reviews IoCs Amendments

EU CTR Release v1.1

- Additional search filters (rare diseases)
- Ability to multi-select in search filters
- Download of published data (plain text)
- User interface improvements
  - Ability to “Bookmark” URLs , including searches
  - Ability to send URL links in emails
  - Fix to allow use of browser “Back” button
  - Better support for other browsers
- Introduction of Really Simple Syndication (RSS) Feed e.g. Subscribe to EU CTR searches
- Internal pilot of improved searching using synonyms from thesaurus database

Statistics
Number of CTs published:

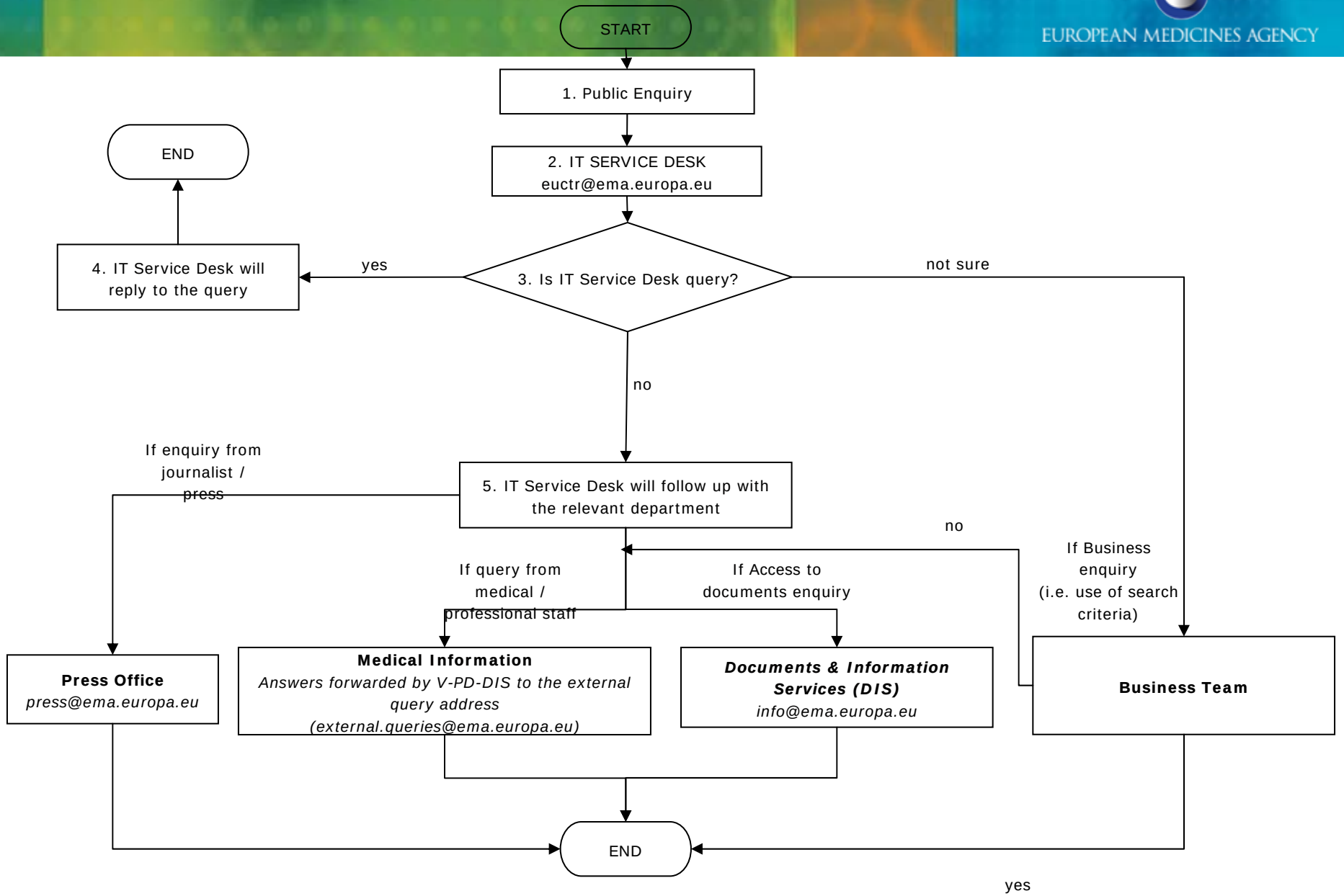
As of 2nd Feb 2012 **16450 public CTs** of which



- Number of clinical trials with subjects less than 18 years old: **2095**
- more than **32,068** distinct CTs of which around 10,127 are phase I trials conducted in adults and therefore they will not be made public.

This refers to the number of distinct CTs available in the EU-CTR (No. of protocols).

EU-CTR Query Workflow



Ongoing Results related activities

- Limited standardisation of data elements, often in development (ISO, CDISC, HL7 Clinical Trial Registry and Results, ICH E3)
- Development of data structure and standards for Results information requires:
  - Data standard
  - XML standard – single sponsor source to multiple registry destinations
- The structure of the data to be collected is mapped to those of ClinicalTrials.gov

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

WHO International Clinical Trials Registry Platform (ICTRP)

WHO - ICTRP

- The EU-CTR has been recognised as a primary registry of WHO ICTRP (International Clinical Trials Registry Platform)

- Information from the EU CTR will be available via the ICTRP next week
- It is an endorsement of the EU-CTR as a source of information for potential study subject as well as for sponsors, ethics Committees and policy makers
- It will help authors submitting trial papers to the leading medical journals since the ICMJE (International Committee of Medical Journal Editors) requires trials to be registered prospectively in a Primary Registry prior accepting an article for publication

- As a primary registry of ICTRP, EU CTR is therefore recognised by ICMJE

http://www.who.int/ictrp/en/

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Demo

https://www.clinicaltrialsregister.eu/index.html

Thank you for your attention!

New Legal requirements

Art. 57 (R 726/2004)	Art. 41 (R 1901/2006)
• Phase II-IV adult trials conducted in the EEA	• Phase I-IV paediatric trials + third country trials in a PIP (including phase I trial in adults that are part of PIP)
This applies to:	This applies to:
• Trials of products with or without MAA	• Trials of products with or without MAA

Protocol-related information

Art. 57 (R 726/2004)	Art. 41 (R 1901/2006)
Submitted by sponsor, at time of CTA submission and entered by NCAs at the time of a valid application	The same or by PIP addressee via EMA for non-EU trials and submitted no later than 1 month after EMA PIP decision or trial approval by third country, whichever is the later
Made public at the time of the clinical trial authorisation (NCA and Ethics Committee)	Made public at the time of clinical trial authorisation/refusal by Ethics Committee

Results-related information

Art. 57 (R 726/2004)

- Submission by sponsors within one year of the end of the trial, via European Medicines Agency
- XML file via the web interface provided by EMA or using a gateway technology
- No review prior to publication- clear disclaimers re content and context
- Available within 5 working days

Art. 41 (R 1901/2006)

- Submission by sponsors, PIP addressee or MAH via EMA within 6 months of completion of trials
- The same for the rest