The Clinical Trials Regulation EU No 536/2014: and Phase I trials

EUFEMED, Brussels, 20 May 2015
A little bit of history

- **1965** - Directive 65/65/EC founds European pharmaceutical legislation but excludes medicines used for research purposes from its scope
- **1990** - EC GCP published
- **1991** - Directive 91/507/EC studies included in MAA to be run to GCP
- **1991** - Commission discussion paper on a future clinical trials legislation
- **2001** - Directive 2001/20/EC published includes clinical trial authorization and GCP and GMP requirements for IMPs in European Pharmaceutical legislation
- **2004** - Directive 2001/20/EC comes into force
- **2012** - Commission proposal for a Regulation on clinical trials
- **2014** - Regulation (EU) N0. 536/2014 is published

And now .......Europe’s opportunity to enhance its global status as the base for innovation in clinical research and medicines development
Phase I trials in EU – data from EudraCT

Clinical Trial Regulation and EU portal and database

EU portal and database and Phase I trials – other aspects
Phase I trials in EU – data from EudraCT

Clinical Trial Regulation and EU portal and database

EU portal and database and Phase I trials
No of CTs by Comm vs Non-comm by year (2005 to 2014) and by phase (I-IV)
### Clinical Trials per Number of Member States Involved and Year, Commercial Sponsor

| Year | 1  | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | Total |
|------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-------|
| 2005 | 1,873 | 251 | 174 | 102 | 94 | 65 | 71 | 44 | 32 | 19 | 26 | 16 | 5  | 8  | 8  | 1  | 5  | 1  | 2,795 |
| 2006 | 1,892 | 222 | 139 | 117 | 96 | 78 | 72 | 43 | 33 | 31 | 25 | 16 | 16 | 15 | 11 | 5  | 6  | 4  | 4  | 2  | 2  | 1  | 2,833 |
| 2007 | 1,937 | 237 | 159 | 137 | 94 | 88 | 69 | 69 | 50 | 35 | 33 | 28 | 19 | 21 | 15 | 6  | 2  | 7  | 1  | 2  | 2  | 1  | 3,013 |
| 2008 | 1,754 | 226 | 153 | 119 | 97 | 85 | 70 | 59 | 46 | 37 | 31 | 30 | 18 | 14 | 11 | 7  | 6  | 5  | 3  | 3  | 2  | 3  | 2,782 |
| 2009 | 1,665 | 201 | 174 | 111 | 96 | 91 | 65 | 53 | 47 | 25 | 27 | 18 | 26 | 9  | 18 | 3  | 7  | 3  | 3  | 4  | 1  | 1  | 2,648 |
| 2010 | 1,566 | 193 | 158 | 96  | 112 | 87 | 72 | 57 | 60 | 36 | 39 | 17 | 23 | 8  | 11 | 7  | 11 | 9  | 6  | 7  | 3  | 2  | 1  | 1  | 2,582 |
| 2011 | 1,228 | 194 | 143 | 103 | 121 | 70 | 65 | 66 | 64 | 38 | 23 | 23 | 15 | 14 | 12 | 5  | 4  | 3  | 3  | 1  | 1  | 2,195 |
| 2012 | 1,292 | 160 | 129 | 119 | 99 | 79 | 61 | 61 | 42 | 43 | 29 | 18 | 22 | 10 | 12 | 11 | 5  | 2  | 2  | 1  | 2  | 1  | 2,202 |
| 2013 | 1,105 | 170 | 116 | 116 | 78 | 81 | 90 | 53 | 40 | 25 | 21 | 12 | 19 | 16 | 10 | 9  | 4  | 1  | 2  | 3  | 2  | 1  | 1  | 1,975 |
| **Grand Total** | 14,312 | 1,854 | 1,345 | 1,020 | 887 | 724 | 635 | 505 | 414 | 289 | 254 | 178 | 165 | 115 | 108 | 54 | 50 | 35 | 24 | 22 | 10 | 10 | 7  | 6  | 2  | 23,025 |

### Clinical Trials per Number of Member States Involved and Year, Non-Commercial

| Year | 1  | 2  | 3  | 4  | 5  | 6  | 7  | 8  | 9  | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | Total |
|------|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-------|
| 2005 | 1,094 | 35  | 17  | 8   | 7  | 6  | 4  | 2  | 1  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | 1,176 |
| 2006 | 1,387 | 50  | 19  | 11  | 7  | 3  | 6  | 3  | 2  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | 1,490 |
| 2007 | 1,903 | 56  | 34  | 15  | 2  | 1  | 4  | 1  | 1  | 1  | 2  |    |    |    |    |    |    |    |    |    |    |    |    |    | 2,021 |
| 2008 | 1,768 | 34  | 21  | 14  | 8  | 3  | 1  | 1  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | 1,850 |
| 2009 | 1,873 | 44  | 19  | 10  | 4  | 5  | 2  | 2  | 1  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | 1,962 |
| 2010 | 1,706 | 38  | 19  | 9   | 2  | 4  | 4  | 1  | 3  | 2  | 1  |    |    |    |    |    |    |    |    |    |    |    |    | 1,791 |
| 2011 | 1,460 | 31  | 17  | 9   | 7  | 3  | 8  | 3  | 1  | 1  | 1  |    |    |    |    |    |    |    |    |    |    |    |    | 1,541 |
| 2012 | 1,700 | 43  | 22  | 12  | 10 | 4  | 1  | 3  | 1  | 1  | 4  |    |    |    |    |    |    |    |    |    |    |    |    | 1,801 |
| 2013 | 1,309 | 37  | 20  | 9   | 6  | 3  | 5  | 3  | 1  |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    | 1,394 |
| **Total** | 14,200 | 368 | 188 | 97  | 53 | 32 | 33 | 19 | 12 | 5  | 9  | 4  | 2  | 2  | 1  | 1  | 1 | 15,026 |
### Planned Patients by Year by Phase by Sponsor Status (F.4.2.1)

This report contains the number of Planned Patients by Year, by Phase and by Sponsor Status in the EEA (section F.4.2.1)

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**Grand Total:** 211,733

**Phase II_EEA Total:** 600,639

**Phase III_EEA Total:** 2,336,197

**Phase IV_EEA Total:** 417,460

**Total:** 828,455
no of Bioequivalence CTs

Year

- Commercial
- Non-Commercial
Phase I trials in EU – data from EudraCT

Clinical Trial Regulation and EU portal and database

EU portal and database and Phase I trials
Regulation Key components and objectives

• Scope (unchanged) – interventional clinical trials of medicinal products

• Single EU portal and database to support:
  • One application dossier for each clinical trial or modification to it
  • Coordinated approach to clinical trial authorization and supervision
  • Transparency of clinical trial authorization, conduct and results

• Protection of trial subjects, including special provisions to enable trials in emergency situations and cluster trials

• Streamlined safety reporting for SUSARs and Annual Safety Reports

• Proportionate approach to trial supervision and conduct
Single EU portal and database

One clinical trial application form and supporting dossier to cover:

- One or more Member States, and all regulatory and ethics assessment
- Public registration of the trial and its subsequent updates, including the necessary elements of international registration at WHO ICTRP portal
- Providing the trial design elements to support subsequent entry and publication of the summary of results

EU substance and product numbers to identify products and substances to underpin linking and aggregation of information on IMPs (with MA via art 57, without MA EU number provided via CT system before or during CT assessment)

EU trial number – one per trial
Authorisation procedure

- Part I – including joint assessment for trial in more than one MS (role of the RMS) + Part II national part
- Single assessment of Part I with single set of questions and responses and single outcome, regardless of the number of MS involved (1-28),
- Combines and consolidates best expertise of the MS involved
- Strictly defined timelines
- Ethics committees involved in the assessment in parts I and II as applicable according to the law of the MS concerned (no derogation from timelines)
- Single decision per MS (including regulatory and ethics review) in line with coordinated assessment of Part I
- Tacit approval if the MS fails to comply with deadline
Clinical Trial Programme
CT regulation timelines/key milestones

- **Final regulation published in OJ**
- **27 May 2014**

- **Functional requirements for audit agreed by EMA MB**
  - 18 Dec 2014: FS to be audit (excl. transparency)
  - 19 Mar 15: features to support making information public

- **System ready and available for audit**

- **EMA MB agrees system is functional**

- **EC publishes confirmation in OJ**

- **Application of Regulation**
  - 6 months
  - Not earlier than 28 May 2016

- **End of legacy period (May 2019 as earliest)**: remaining on-going trials governed under Directive 2001/20 switch to new regulation

- **Transition Period of 3 years start**
  - Oct 2015: the rules and criteria on what data and documents are to be made public, and on the timing of that publication

- **Regulation applies 6 months after the publication of the confirmation note in the OJ and not earlier than 2 years after the publication of the Regulation (not earlier than 28 May ’16)**

- **Not earlier than 28 May 2016**

Clinical Trial Programme

The Agency has to deliver, maintain and update the IT platforms needed for the implementation as required by regulation:

- EU portal and database and medicinal product dictionary (Art. 80, 81, 82 and 84)
- Safety reporting (Art. 40 and 44)
- EudraCT and EU CTR legacy (Art. 98)
- A data warehouse is considered part of these projects to facilitate the reporting and link of CT related information within each system or among them.
CT Programme: governance

**MSs, EMA, Commission**

**Management Board**

**Member States and Commission**

**EU Clinical Trial’s Information System Expert Group**

**Stakeholders**
- Sponsors
- CROs
- Patient organisation
- HCPs

**Project Subgroups**

**Stakeholders**
- Sponsors
- CROs
- Patient organisation
- HCPs

**EMA**

**Programme Manager**

**EU Telematics**

**IT Directors Executive Committee**

**EU TMB**

Meetings four times per year (first meeting took place on 25th of June)

Regular meetings (stakeholders involved since October 2014)

- Sponsor driven activities
- Member state driven activities
- User management
- Provision to public
- Inspections
- EU control
- Clinical trial safety reporting
EU portal and database
CT Programme: medium level view

PORTALS | WORKSPACE | DATABASES
---|---|---
EU Portal | Workspace | EU Database
Safety Portal & SUSAR ASRs | | Document & Data Repository of CT Information
Other Portal | | EVCTM

Scope of article 82 functional specifications and audit

Out of scope of article 82 functional & audit

Public internet access to information

Interface with MSs CT systems

User registration and assignment required
EU portal and EU database: “To be” process

EU Single Portal

Submission of CSR
Applicant of a MAH

Submission of Union Control Reports
Commission

Key:
- Applicant of a MA Workspace
- Sponsor Workspace
- MS/Commission Workspace
- Public module

Notification of willingness to be RMS (Part I) / decision on RMS
Submission of requests for information
Notification of the final validation (initial, additional MS or substantial modification)
Submission final AR Part I and Part II
Final single decision notification
Communication disagreement to Part I assessment
Communication on implementation of corrective measures
Submission inspection information
Search and view all CT related information saved in the EU database

Submit submission package (CTA & dossier)/ address request for information
Submission to the medicinal product dictionary
Submit notifications:
- Withdrawal
- Start of trial
- First visit first subject
- End of recruitment
- End of trial (in each MS, all MS, global)
- Temporary halt
- Restart of the trial
- Early termination
- Serious breaches
- Unexpected events which affect risk/benefit
- Urgent safety measures

Submission of clinical study result summary
Submission of inspection reports of third country authorities
Update of CT information regarding non-substantial modifications
Transparency legal requirements: Clinical Trials Regulation

Article 81(4) of Regulation (EU) No. 536/2014

- EU database publically accessible by default, with exceptions justified on any of the following grounds:
  - Protection of personal data;
  - Protection of commercially confidential information in particular taking into account the MA status of the medicinal product, unless there is an overriding public interest in disclosure;
  - Protecting confidential communication between MS in relation to the preparation of the assessment report;
  - Ensuring effective supervision of the conduct of a clinical trial MSs.
Clinical Trials Regulation: public disclosure of information

- Have all clinical trials been publicly registered?
- Is there a trial in which I could participate?
- What was the outcome of the trial I did participate in?
- What trials were the basis of the marketing authorisation, what were their results?
- What is known about the medicine I am taking/prescribing?
- Can we review the data used to support the marketing authorisation?
- Has the trial we are designing already been conducted? Were there problems with similar trials?
Functional specifications of EU portal and database

- Strike the right balance between:
  - respecting patients’ and doctors’ needs and the publics’ entitlement to extensive and timely information about clinical trials;
  - and developers’ and researchers’ need to protect their investments;
  - a balanced approach is needed to protect public health and also foster the innovation capacity of European medical research.
Functional specifications of EU portal and database

- “Functional specifications for the EU portal and EU database to be audited” final published 19 December 2014
- “Draft proposal for an addendum, on transparency, to the 'functional specifications for the EU portal and EU database to be audited”
  - Public consultation from 21 January 2015 – 18 February 2015
- Seek stakeholders’ views on the application of these exceptions set out in article 81 of the Regulation
What is being made public:

- At the time of decision on the trial:
  - the main characteristics of the trial (as set out in the clinical trial application form - being in effect a structured synopsis of the clinical trial protocol) – similar to what appears in EU CTR or clinicaltrials.gov
  - Information on investigator sites
  - the protocol summary
  - the conclusion on the assessment of Part I of the trial
  - the decision on the trial including reasons for refusal if the trial is not authorised (or where applicable the reason for its withdrawal)
  - the start of the trial
What is being made public:

- **During the trial:**
  - the first visit of the first subject in the trial in each MS concerned
  - substantial modification of the trial
  - temporary halt or early termination of the trial
  - notification on the end of recruitment in each MS concerned
  - end of the trial
  - other documents and notifications set out in Regulation (inspections, safety measures, serious breaches ...)

- **12 months After the end of the trial:**
  - summary clinical trial results and lay summary

- **30 days After Completion of the Marketing Authorisation process (whatever the outcome):**
  - the clinical study report for trials authorised under the new Regulation and included thereafter in a MA dossier
What is being made public:

- All information in the database will be public with the exception of the IMPD quality/manufacturing section and its related assessments, and the financial contracts between investigators and sponsors.
- Timing of release of details of phase I trials may be deferred until 12 months after the trial (and published with the summary results).
- Protocols, subject information sheets, IMPDs and investigator brochures, may be deferred differentially dependent on the nature of the IMP and of the trial.
- Results of trials are proposed to be made public as foreseen:
  - 12 Months after the end of the trial – summary results and layperson summary.
  - 30 days after the decision on marketing authorization or its withdrawal by the applicant – the clinical study report of trials authorized under this Regulation and included in a EU marketing authorization application (central or national).
Disclosure of information from the EU database
Three groups of clinical trials can be identified – based on the nature of the IMPS being studied and what is being studied

- Phase I trials in healthy volunteers and patients - include so called phase 0, BE and BA studies for novel product or generics/biosimilars, new formulations or indications
- Therapeutic (or prophylactic or diagnostic trials) in target population on indications or formulations outside of the authorised uses
- Post authorisation trials that are either phase IV within the terms of the Marketing Authorisation or are established medical practice in one of the Member States concerned (includes Phase IV and low-intervention trials)
Proposal regarding Information to be made public at the time of decision on the trial – possible deferral for Phase I trials in healthy volunteers (see 4.2.).

Proposed option for sponsor to choose to defer publication of major characteristics of the trial for Phase I, from the default “at time of decision on trial” (and updates during the trial), to the time of publication of the summary of results, 12 months post end of the trial.

End of trial defined as: Article 2(26) ‘End of a clinical trial’ means the last visit of the last subject, or at a later point in time as defined in the protocol;

- Allow time for filing of patent applications. In addition timing of disclosure of protocol, subject information sheet, IMPD and IB till later point either at time of MA using that clinical trial or a fixed number of years after the end of the trial.
- Allow sponsors to undertake first steps with a new product or formulation with limited disclosure. But maintain public disclosure of clinical trial information and summary results.
Next steps

1. Revised section 6 of the “Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014” setting out technical features to support making information public was endorsed by Management Board on 19 March 2015.

2. EMA in close collaboration with the MSs and the European Commission will revise and agree the rules on transparency, i.e. the choices to be made on publication of information following the consultation.

3. The agreed rules will be submitted for endorsement in the October 2015 Management Board.

4. Perform a “Privacy Impact Assessment” in parallel
Phase I trials in EU – data from EudraCT

Clinical Trial Regulation and EU portal and database

EU portal and database and Phase I trials – other aspects
Non-EU sponsor - Article 74
Legal representative of the sponsor in the Union

1. *Where the sponsor of a clinical trial is not established in the Union, that sponsor shall ensure that a natural or legal person is established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that legal representative shall be deemed to be a communication to the sponsor.*

2. *Member States may choose not to apply paragraph 1 as regards clinical trials to be conducted solely on their territory.....provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that clinical trial who shall be the addressee for all communications with the sponsor provided for in this Regulation.*
Medicinal product dictionary

Phase I trials and in particular first in human trials will often be the first contact between a particular active substance/IMP and the EU medicinal product dictionary.

Process for sponsor to register product and substance in dictionary – before the trial or as part of the clinical trial application.

Substance and product numbers used as key for data quality linking trials, adverse reaction data and other information on medicines.
User Access and management

- Sponsor applies for a clinical trial via the portal, or
- Sponsor designates a CRO to make application, CRO accesses portal,
- Sponsor (if registered) or CRO can delegate users and access to data and portal
- Sponsor can authorize cross reference to core documents initially filed with another clinical trial application
Conclusion

A real opportunity for EU to innovate and to lead

- in clinical trial regulation and
- in innovation of new medicines and better use of existing medicines,

Streamlined, coordinated, proportionate and transparent

- Single electronic submission of data and documents to cover trial application, modification, registration and results reporting
- Streamlined and coordinated clinical trial between and within MS, using best expertise in the MS concerned
- Streamlined safety reporting,
- Proportionate supervision of clinical trials,
- Transparency supporting public confidence, participation and critique and enabling innovation.
Thank you for your attention

Further information
Contact me at Fergus.Sweeney@ema.europa.eu

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