

New Clinical Trial Regulation and clinical research in Academia

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Clinical Trial Facilitation Group
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Why need to regulate Clinical Trials?

- A Clinical Trial (CT) can be conducted, if
 - The **rights, safety, dignity, and well-being** of **SUBJECTS are protected** and prevail over all other interests
 - It is designed to **generate reliable and robust DATA**

(Art 3, EU Clinical Trial Regulation 536/2014, (CTR))

- **Positive benefit risk balance**

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Regulatory body : Responsibilities II

- While supervision may ask for **Corrective Measure**:
 - Any modification
 - Halt (suspend authorization) or
 - Stop (revoke authorization) of a clinical trial, if the positive benefit risk no longer given
- Initiate and perform **inspection** of a clinical trial (e.g. GCP, pharmacovigilance)
- Status of a CT and final results of a clinical trial uploaded in EU/global **database/register** for transparency to general public

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Why Clinical Trial Regulation EU 536/2014 (CTR)?

- Europe EU/EEA 30 Member States
 - Directive 2001/20/EC *transferred* into 30 (different) national laws
- Harmonisation in EU/EEA
- Regulation (= replacing national laws for competent authorities and ethic committees in Member States)
- No national interpretations or additions possible
- Control by European Commission
- Simplification for sponsor (not Member States)

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What is CTR 536/2014 about?

- **Matter of ONE**
 - 1 Single application procedure for mono- and multinational CTs, including substantial modifications
 - 1 Communication hub : ,EU Portal and database'
 - 1 Lead MS in part I: Reporting Member State (RMS)
 - 1 Set of documents
 - 1 Joint assessment (part I) of all concerned MS (MSCs)
 - 1 Decision per application per MS
 - 1 Fee per MS
- Add more MSC after first authorization

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CTR EU 536/2014 – Other Changes?

- Fixed maximum tight **timelines** in EU
- **New concept of Clinical Study** :
any investigation in relation to humans intend to indentify:
 - a) Pharmacological or pharmacodynamic effects of medical product/s
 - b) Adverse reaction to medical product/s
 - c) ADME of medical product/s
- **Clinical Trial**
 - a) Assign to therapeutic strategy in advance...
not within normal clinical practice of the MSC
 - b) Decision to prescribe the IMPs together with decision to include in CT
 - c) Diagnostic or monitoring procedure in addition to normal clinical practice
- **Non interventional clinical trial** is a clinical study
but other than clinical trial

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CTR EU 536/2014 – Other Changes II

- **Low interventional trial**, if
 - IMP is authorized, except placebo
 - IMP used within terms of marketing authorization, or
 - Off-label use is evidence based and supported by published scientific evidence on safety and efficacy in any MSC
 - Additional diagnostic or monitoring procedures no more than minimal additional risk or burden to the safety of participants compared to normal clinical practice in any MSC
 - ... Insurance
- **Emergency situations** without prior informed consent
- **Cluster trials**
- **Informed consent** : subjects without decision-making capacity

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CTR EU 536/2014 – Other Changes III

- **Transparency**: Protocols, results, assessment
 - Improve Research
- IT system prerequisite to get CTR applicable
EU Portal and Database (EUPD) training by EMA
- Commission collects survey
on national support for academic researchers
- MS:
 - **No change in content of assessment** (jointly)
 - Change in timelines for all stakeholders
 - Only one application per CT – One decision per MS

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- Working group of Head of Medicines Agency (HMA)
- Network of NCA's initiated with Directive 2001/20 on CTs in 2004
- Tasks/Actions: The 'body' for CTs in EU/EEA
 - Support, **harmonize and facilitate CTs in EU/EEA**
 - Develop harmonized **procedures**
 - **Common positions** on regulatory or scientific issues
 - Support development of **guidances**
 - Support **implementation of EU CTR 536/2014**
 - *Readiness* of NCAs/MSs for CTR
 - Development of EUPD/CTIS

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- Develop **harmonized (coordinated) procedures**
 - Voluntary harmonisation procedure (VHP)
 - VHPplus (plus Ethics)
 - Annual safety report work sharing
 - Safety relevant issue
- **Common positions on regulatory or scientific issues**, e.g.
 - Contraception in CTs
 - Reference safety information, annual safety report (DSUR)
 - In work - Complex CT design
 -

<http://www.hma.eu/ctfg.html>

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- Support implementation of CTR
 - **Tracking** readiness of NCAs/MSs with ,traffic lights‘
 - **Best Practice** of MSs on procedures, definitions
 - **Assessment Report Templates**
 - Initial draft assessment report (AR) and final AR
 - Annual Safety Report AR
 - **Guidance** support, e.g.
 - COM's risk based approach
 - AxMP (former NIMPs)
 - QnA safety

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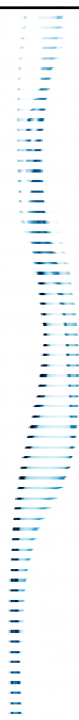
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- ...Support implementation of CTR
 - Development EU portal and database
- In future, further facilitates CTs in EU/EEA
 - Coordinated harmonisation and opinions
 - Regular exchange with **ALL** stakeholders
 - Burning issues and horizon scan
 - Scientific and regulatory opinions of aspects in CTs of general interest

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Overall,

- CTR EU536/2014 will mainly harmonise (simplify EU-wide) your way of working, not content of work!
Additional study types are addressed as well as special populations
- CTFG is the body for CTs in EU/EEA
CTFG facilitates and coordinates CT relevant issues, and harmonises positions to CT related topics of interest

The logo consists of a vertical line of blue dots of varying lengths, creating a wavy, stylized shape.

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