HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Good Clinical Practice, Investigational Medicinal Product Trials

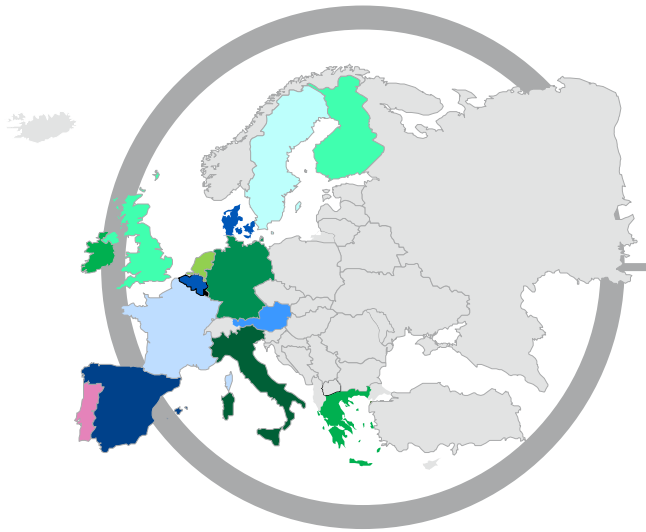
Update on Clinical Trials Regulation EU No 536/2014

Dr. Agnieszka Przybyszewska

Dublin, 23 Oct 2018

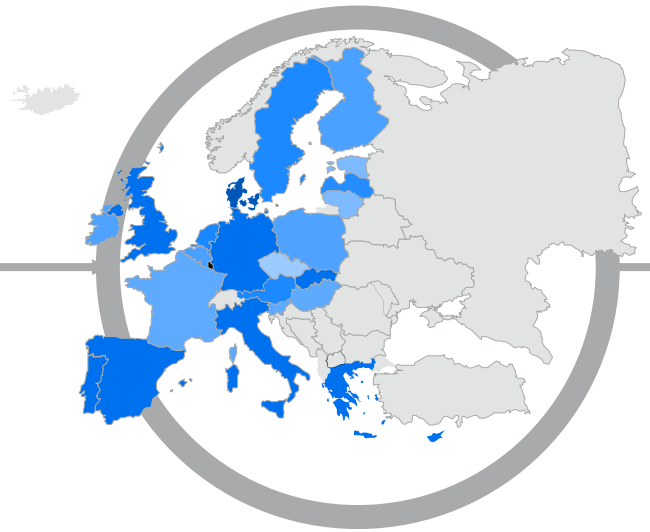
HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Before May 2004



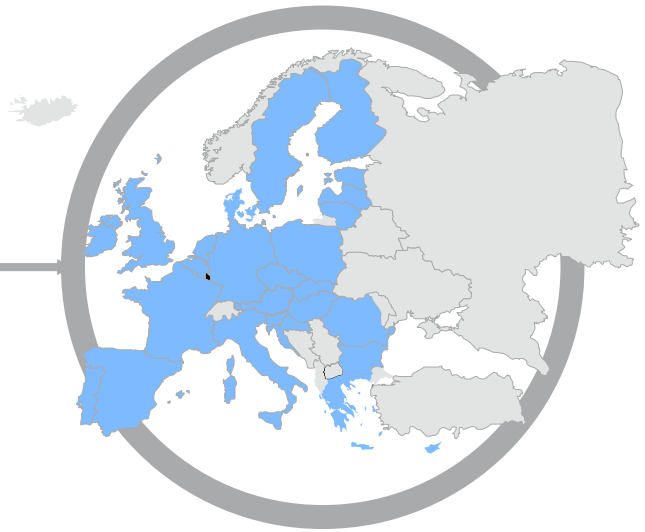
Different processes and requirements

Directive 2001/20/EC



First step to harmonize

Regulation 536/2014



Published in 2014

Objective of the Regulation

- To protect the rights, safety, dignity and well-being of subjects and the reliability and robustness of data generated in the CT
- To foster innovation and simplify the clinical trial application process
- To increase transparency, keeping the balance between protection of public health and fostering innovation capacity of European medical research while recognising the legitimate economic interests of sponsors

Let's review main differences between Directive and Regulation

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

	Submission	Assessment	Transparency
Directive 2001/20/EC	Multiple submissions for one trial/no harmonized dossier	Individual assessment by each MSC with no IT collaboration tool available NCA and Ethics committees independent assessment	Limited EudraCT data availability to the public: structured data from the application (CTA) and summary of results
Regulation 536/2014	Single e-submission to all MSCs/harmonized dossier for one trial	Joint assessment for Part I facilitated by collaboration tools Single MSC decision	Increased transparency

Implementation of the Regulation depends on the development of EU portal and database

Application 6 months after confirmation published in the OJ of full functionality of EU portal and EU database.

The system could be ready to go live later in 2020.

National implementation of the Regulation

- Regulations have binding legal force
- Specific national legislation still required as the Regulation defers to national legislation for detailed requirements:

Role and composition of ethics committee	Informed consent: for who can take consent, who can provide consent	Incapacitated subjects: more stringent rules in national legislation
Legal Representative: MS can opt out and request a contact person only	Insurance/indemnity arrangements	Inclusion of prisoners, care home residents, military personnel
Investigator must be a medical doctor: unless national law specify	MS lay down penalties	Medical files archived as per national legislation

Implementation in Ireland

Clinical Trials Regulation (EU) No. 536/2014 Pilot Project

Joint assessment
Part I
HPRA, ethics committee

Voluntary for
Sponsors

HPRA
"submission portal"

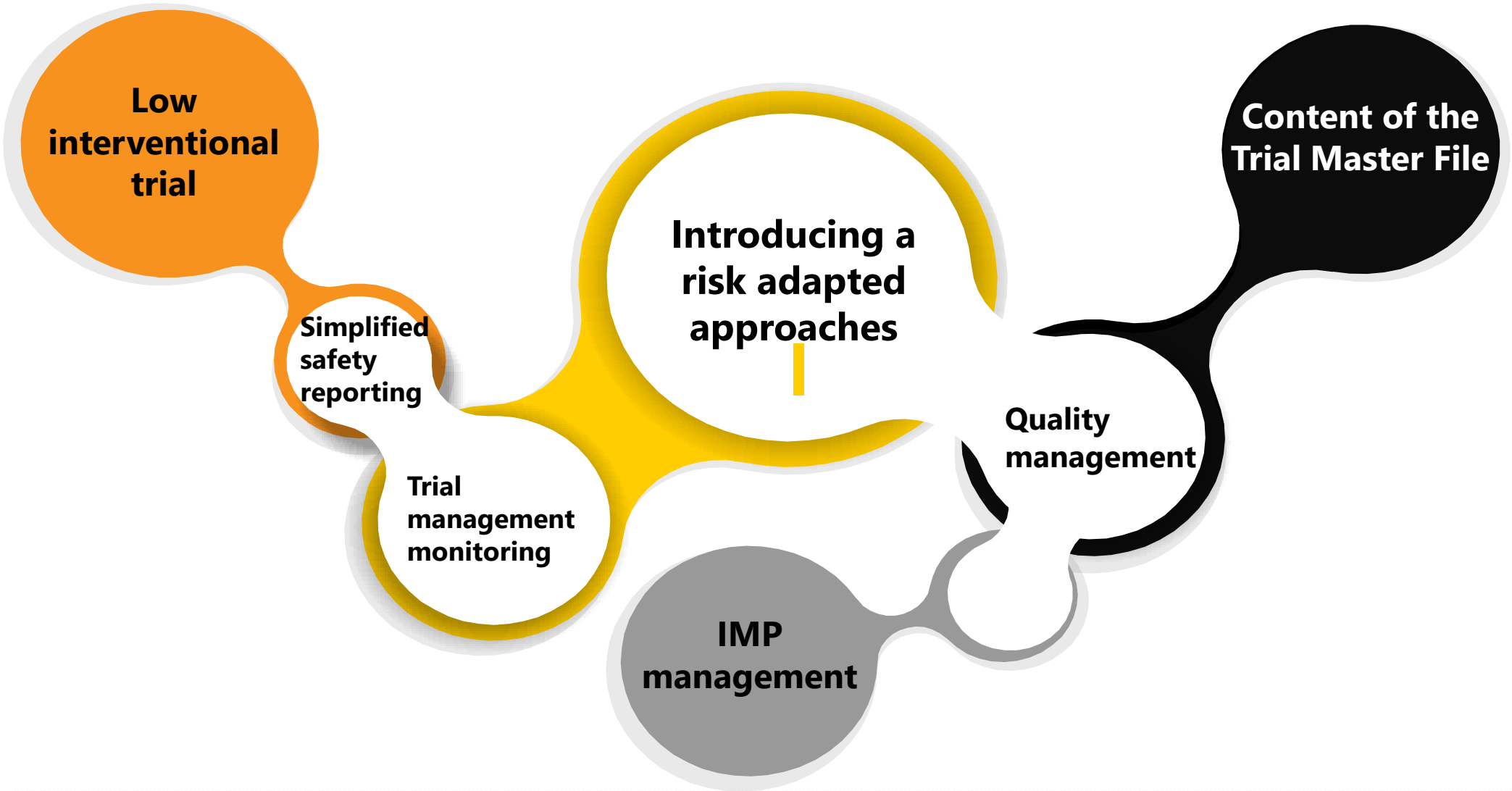
4 clinical trials

Guide to Clinical Trials Regulation (EU) No. 536/2014 Pilot Project - Ireland

The sponsor of a clinical trial and the investigator shall ensure that the clinical trial is conducted in accordance with the protocol and with the principles of good clinical practice

Article 47, Regulation 536/2014

GCP related changes in the Regulation



Other GCP related changes	Mandatory reporting of serious breaches
	Content of the trial protocol is defined by Annex I of the Regulation
	Publication of inspection reports

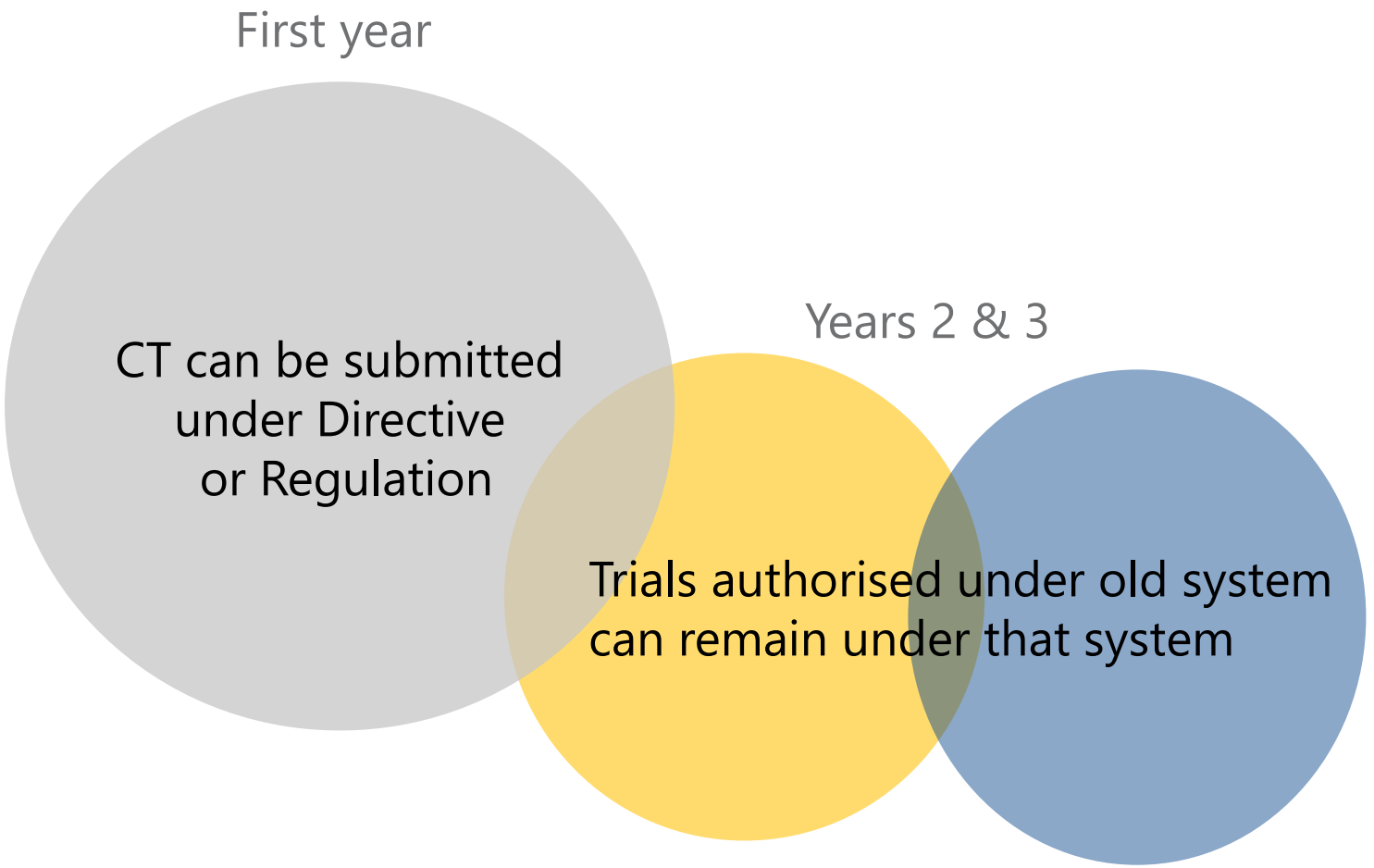
Transparency- Balancing between public interest and sponsor's economic interest

Introduction of trial categories

Depending on the category of trial the sponsor can defer publication of certain data and documents up to a maximum time limit

Appendix, on disclosure rules,
to the "Functional specifications for the EU portal and EU database to be audited - EMA/42176/2014

Transition period



All CTs to switch to new Regulation 3 years after implementation. Voluntary earlier transition possible

CTFG Best Practice Guide for sponsors of multinational clinical trials with different protocol versions approved in different Member States under Directive 2001/20/EC that will transition to Regulation (EU) No. 536/2014

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Thank you