Medicinal products and medical devices in clinical trials conduct and disclosure – and never the twain shall meet!

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Abstract
"Medicinal products and medical devices are different species…they live in parallel universes" according to a medical device expert. But is it really so? This article challenges that notion by comparing the Clinical Trial Regulation EU No. 536/2014 (CTR) and the EU Medical Device Regulation 2017/745 (MDR) in the context of clinical studies and public disclosure. Despite some fundamental differences, similarities and overlaps in the requirements and details between the CTR and MDR are evident. There is also a clear aim for the electronic databases, as described in the two regulations, to be interoperable. This high-level comparison of the CTR and MDR shows that while the *requirements* of the two regulations have been aligned and are very similar, their *impact* on the respective industries is quite different.

Two parallel universes
"**WARNING**: Medicinal products and medical devices are different species. They live in parallel universes. They may appear similar ("medicinal products"), but they are not. **Carelessly switching between universes may be deadly**." These words are taken from a presentation by Ronald Boumans, a Senior Regulatory Consultant at Emergo Group.[1] Jokes aside, after evaluating the two regulations, we are compelled to challenge this statement. As professional regulatory medical writers who have been developing regulatory documents for both pharmaceutical drug products and medical devices for many years, we already switch between these universes and firmly believe that linking these two is not only feasible but also profitable, as other colleagues can also attest.[2] Nevertheless, the school of thought that "a drug is a drug, a device is a device, and never the twain shall meet" is relatively widespread.[3]

Two universes, two regulations
In 2014, the Clinical Trial Regulation European Union (EU) No. 536/2014[4] (henceforth referred to as CTR) was released. The detailed requirements and documentations of this legislation were really nothing new for the pharmaceutical industry. The major changes were the centralised clinical trial application, the increased disclosure requirements, and the setting up of a new EU portal and database (to replace the existing ones).

In 2017, the EU Medical Device Regulation 2017/74[5] (henceforth referred to as MDR) was released. Literally "left to its own devices till now",[3] the medical technology industry struggles with the drastically increased and unfamiliar regulatory requirements of this legislation.[6,7] Following the thread of Bouman's analogy, it felt like aliens had invaded the medical device universe.

As professionals working for the two industries, we were obliged to familiarise ourselves with these two new legislations. This article makes a high-level comparison between the CTR and the MDR (Table 1) based on the original texts of the legislations and the authors' interpretation of those texts built on their experiences of working in the pharma and medical device industry. The comparison is focused on the conduct and disclosure of clinical studies, often referred to as clinical *trials* for medicinal products and as clinical *investigations* for medical devices.

Obvious differences

The most obvious difference is the scope of the two regulations. The CTR, as its name implies, covers interventional clinical trials for medicinal products and supersedes Directive 2001/20/EC and Paediatric Regulation (EC) No. 1901/2006. The purpose of the CTR is to add clarity to the previous laws as well as simplify and harmonise the administrative processes for clinical trials performed in the EU/European Economic Area (EEA). Other regulatory aspects of CTR, such as market authorisation and pharmacovigilance, are covered by the Directive 2001/83/EC and Regulation 726/2004.

The MDR, on the other hand, has a much broader scope than the CTR and goes beyond clinical investigations by including manufacturing, market access, and post-market vigilance. MDR supersedes two Directives, 90/385/EEC (active implantable devices, 2007) and 93/42/EEC (other devices, 2007). The main objectives of the MDR are "to establish a robust, transparent, predictable, and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation [and] to ensure the smooth functioning of the internal market as regards medical devices . . ."[5]

The other important difference is that under the CTR, the EMA ("the Agency") has the major responsibility of implementation, with support from the European Commission (EC) and the member states. For the MDR, the major responsibility of the implementation lies with the EC, working together with the competent authorities of the EU member states.

Similarities and overlaps

The MDR and CTR were written three years apart and our initial reaction when we first read the MDR was that the two universes are coming together, especially when it comes to clinical study conduct, reporting, and disclosure, as summarised below and also in Table 1 (that compares the CTR and MDR).

Clinical study conduct

Clinical evidence is needed for new health products to be granted market access. Clinical studies (trials or investigations) are performed to collect data on efficacy and safety of the tested products. The CTR and MDR are relatively aligned in their definitions of clinical trials and investigations, respectively, as well as in respect of the key involved stakeholders (Table 1). In some cases, the terminologies used differ slightly while the definitions are almost identical. In general, it seems that fewer clinical studies are needed for approval of a new device than for a new medicinal product.[3]

Clinical study registration

Both CTR and MDR require registration of clinical studies in a publicly accessible registry. Each study must be identified with a unique ID number. This requirement was already covered in the previous legislation for medicinal products but not in the predecessors of the MDR.

In the USA, the database ClinicalTrials.gov provides a clear breakdown of clinical trials by drugs, biologics, surgical procedures, and devices. To date, this kind of breakdown of clinical studies is not readily available for studies performed in the EU or the states of the EEA in the current database, the EU Clinical Trials (CT) Register. Currently, the EU CT Register requires only registration of medicinal products tested in interventional clinical trials with at least one trial site in the EU/EEA and "does not provide information on clinical trials for surgical procedures, medical devices, or psychotherapeutic procedures". The MDR may resolve this information gap, as discussed in the following sections.

The electronic systems and databases

To support the CTR harmonised approach to submission, assessment, and reporting of clinical trials, the EC has mandated the EMA to establish a new EU portal and database according to the specifications in the CTR. Data submitted through the new portal will be stored in an EU database that is open to the public. Duplications with the existing databases (Eudravigilance and

Table 1. Comparison of the requirements for clinical trials/investigations conduct and disclosure under the CTR 536/2014 and MDR 2017/745

	EU CTR 536/2014	**EU MDR 2017/745**
Full name	Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
Scope	Clinical studies in medicinal products: submission, assessment, notification, disclosure	Clinical studies in medical devices: submission, assessment, notification, disclosure (Article 62, Annex XV) Manufacturing, CE-marking (market authorisation), post-market surveillance of medical devices
Definitions of terms related to clinical studies (per CTR or MDR)	**Clinical study**[a]: any investigation in relation to humans [intended to study clinical, pharmacological, pharmacodynamic effects, identify any adverse reactions, study absorption, distribution, metabolism and excretion] … with the objective of ascertaining the safety and/or efficacy of those medicinal products	**Clinical investigation**: any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device
	Investigational medicinal product: a pharmaceutical form of a medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial	**Investigational device**: a device that is assessed in a clinical investigation
	Protocol: a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial	**Clinical investigation plan**: a document that describes the rationale, objectives, design, methodology, monitoring, statistical considerations, organisation and conduct of a clinical investigation
	Sponsor: an individual, company, institution or organisation which takes responsibility for the initiation, for the management and for setting up the financing of the clinical trial	**Sponsor**: any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation
	Subject: an individual who participates in a clinical trial, either as recipient of an investigational medicinal product or as a control	**Subject**: an individual who participates in a clinical investigation
	Investigator: an individual responsible for the conduct of a clinical trial at a clinical trial site	**Investigator**: an individual responsible for the conduct of a clinical investigation at a clinical investigation site
	Informed consent: a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate, or in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial	**Informed consent**: a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the clinical investigation that are relevant to the subject's decision to participate or, in the case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical investigation
Clinical trial / investigation conduct	• Required for all investigational medicinal products	• Required for certain device classes (Class II to III) that do not have a CE mark
Clinical trial / investigation registration	• Obligatory for all studies with at least 1 EU site, submitted via EU portal, stored in the EU database • Unique EU trial number (Article 81)	• Obligatory for all investigations with at least 1 EU site, submitted on the electronic system for clinical investigations within the Eudamed (Article 73) • Unique ID number for each investigation (Article 62) • If the application is submitted in parallel with an application for a clinical trial in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial (Annex XV, Chapter II)

Continued opposite

	EU CTR 536/2014	EU MDR 2017/745
Databases	• EU portal as a single entry point for the submission of data and information relating to clinical trials (Article 80) • Data and information submitted through the EU portal shall be stored in the EU database (Article 81) • Unnecessary duplication between database and EudraCT and EudraVigilance databases to be avoided • Partial public access • European Medicines Agency as controller	• Eudamed that integrates several electronic systems (Article 33) • The electronic system for clinical investigation is the entry point for the submission of all applications or notifications for clinical investigations (Articles 70, 74, 75, 78); for all other submission of data, or processing of data • Partial public access, all public parts should be user-friendly and in an easily searchable format • European Commission is the controller • To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations should be interoperable with the EU database to be set up for clinical trials on medicinal products for human use (Preamble 67)
Public disclosure: Clinical study application	• Protocol, IB, IMPD (S and E), SmPC (Annex I) • Protocol to describe publication policy (Annex I, D 17-ai) Potentially all publicly accessible	• Clinical investigation application dossier (Article 62; Article XV) • Clinical Investigation Plan (CIP), IB (Annex XV) • CIP to contain policy on the CIR and publication of results (Annex XV, Chapter II, 3.17) • Potentially all publicly accessible
Public disclosure: Study results reporting	• Public access via the EU database • A summary of the results of the clinical trial irrespective of the outcome, to be submitted within 1 year (Article 37; Annex IV) • Layperson's summary (Article 37; Annex V) • CSR within 30 days post-MAA decision (Article 37)	• Public access via the Eudamed • CIR within one year of the end of the clinical investigation or within 3 months of the early termination or temporary halt, irrespective of the outcome (Article 77) • Summary easily understandable by a user (Article 77) • Publication of results according to legal requirements and ethical principles (Annex XV, Chapter II; see next row)
Other ethical guidances that can impact disclosure	• Declaration of Helsinki 2008 (Preamble 80) • ICH guidelines on Good Clinical Practice (Preamble 43)	• Declaration of Helsinki latest version (Preamble 64) • ISO14155:2011 (Preamble 64)
Protection of personal data	• Personal data protection per Regulation (EC) No 45/2001 (now replaced by the General Data Protection Regulation (GDPR) 2016/679) • Protocol should describe arrangements for compliance, measures to ensure confidentiality, mitigation measures for security breach adverse effects (Annex I-D)	• Personal data protection per Regulation (EC) No 45/2001 (now replaced by GDPR) • CIP should describe arrangements for compliance; measures to ensure confidentiality, mitigation measures for security breach adverse effects (Annex XV Chapter II, 4.5)
Protection of commercially confidential information (CCI)	• Protection of CCI, unless there is an overriding public interest in disclosure (Article 81, 4a)	• Protection of CCI, trade secrets, intellectual property rights, unless disclosure is in public interest (Article 109, 1(b))

CE: Conformité Européenne; CIR: Clinical investigation report; CSR: Clinical study report; CTR: Clinical trial regulation; EC: European Commission; EU: European Union; Eudamed: European databank on medical devices; EudraCT: European Union drug regulating authorities clinical trials; EudraVigilance: European Union drug regulating authorities vigilance; IB: Investigator's brochure; IMPD: Investigational medicinal product dossier; ISO: International Standardisation Organisation; ICH: International Council on Harmonisation; MAA: Marketing authorisation application; MDR: Medical device regulation

[a] in many instances, the CTR uses the terms study and trial interchangeably.

European Clinical Trials database [EudraCT]) will be avoided. Once the new portal and database are fully functional and implemented (expected to occur later in 2020), the current EudraCT and EU CT registry will be replaced, following a transition period.[8]

The European databank on medical devices (Eudamed), in existence since 2010[9], has been operating in conjunction with the old directives; however, the database was never systematically used for investigations with medical devices. Through the MDR, the Eudamed structure is broadened and its use becomes mandatory under the responsibility and auspices of the EC. Another substantive change in the new Eudamed is the increased transparency of the investigations, requiring the database to be available for public access.

Public disclosure: clinical study application

The publicly accessible information and documentation used for the applications of clinical trials/investigations submitted via the EU portal/Eudamed will include information regarding the sponsor, cclinical study protocol/clinical investigation plan (CIP) and their amendments, investigator's brochure (for both medicinal products and devices), and some sections of the investigational medicinal product dossier for medicinal products.[8] There are exceptions as to what can be disclosed including protected personal data and commercially confidential information (CCI).

Though not clearly described in the legislations, decisions on publication and sharing of results are expected to be described in the clinical study protocol or the CIP as part of the clinical study application.

Public disclosure: clinical study results

Both the CTR and MDR require full disclosure of the clinical study results summary based on the clinical study report (CSR) and clinical investigation report (CIR), respectively. For medicinal products, the CTR requires a comprehensive summary of the clinical study results (technical summary) plus a summary that can be understood by laypersons (layperson summary also known as plain language summary). These summaries will need to be submitted to the forthcoming EU portal and will be available to the public via the EU database after the study ends (12 months for studies with adults and 6 months for studies with participants 18 years or younger at the time of enrolment); *study end* is defined as the date of the last patient's last visit. The CSRs containing summary results of the study will be published 30 days after a marketing authorisation opinion is received (whether positive, negative, or if the marketing authorisation application is withdrawn by the applicant).

The MDR requires a full CIR and a summary of results that can be understood by the intended user (similar requirement as the layperson summary, above). These documents will be submitted to the Eudamed and made available to the public. Unlike the CTR, there seems to be no intermediate step of clinical study results summary posting under the MDR; a CIR is expected within one year of the end of the investigation, defined as the date of the last patient's last visit.

For clinical investigations, the MDR requires that each step, "from the initial consideration of the need for and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles," i.e., ISO 14155:2011 and the most recent version of the World Medical Association (WMA) Declaration of Helsinki (current version dated 2013). The CTR refers to the International Council for Harmonisation guidelines on good clinical practice and the 2008 version of the WMA Declaration of Helsinki. Both versions of the Declaration of Helsinki include clear recommendations on the registration of clinical studies and the publication of research results in publicly accessible platforms.

Personal data protection

The strict requirements to protect the personal data of study participants in documents that will be publicly accessible are mentioned in both the CTR and MDR. Both regulations refer to Regulation (EC) No 45/2001, which has now been superseded by the recently implemented General Data Protection Regulation (GDPR) 2016/679. Under the GDPR, the principle of privacy by design or by default is a key requirement, i.e., all systems and processes should have personal data protection measures integrated into them.

Confidentially commercial information

The CTR and the MDR, respectively, consider the commercial interests of the "pharma" and "medtech" companies by providing possibilities to protect CCI, trade secrets, and intellectual property rights. However, there is a caveat in both regulations: protection of CCIs can be overruled if their disclosure is in the public interest. Experience with documents that fall under EMA Policy 0070 – which facilitates disclosure of numerous 'reports' of approved products – has shown that minimal CCI redactions are accepted by the EMA. Indeed, all redactions of CCIs need to be justified in writing and presented to the EMA for a decision; the EMA has the final word on the acceptance of a CCI to be redacted. It is anticipated that the principles for document redaction that apply to EMA Policy 0070 will also be used for the documents that are required to be disclosed by the MDR.[8]

And the twain shall meet

The CTR focuses mainly on investigational medicinal products (e.g., drugs and biologics) and mentions devices only in the context of medicinal product administration and delivery systems. The MDR, which postdates the CTR by three years, refers to the CTR three times. The MDR recognises that medicinal products and devices may occur together as combined products, a topic that is not addressed in the CTR. However, even outside of the context of combined products, the MDR states that "to ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations [Eudamed] should be **interoperable** with the EU database to be set up for clinical trials on medicinal products for human use." This is presumably part of the EU initiative for standardisation and interoperability of all electronic health systems in Europe.[11] This

To ensure synergies with the area of clinical trials on medicinal products, the electronic system on clinical investigations [Eudamed] should be **interoperable** with the EU database to be set up for clinical trials on medicinal products for human use.

interoperability of the two electronic systems will address the information gap described earlier in our article and allow a more comprehensive record of clinical studies conducted in the EU (regardless of the product type), similar to what is available on ClinicalTrials.gov.

Similar contents, different impacts

We highlight above the similarities between the CTR and the MDR in terms of clinical studies, documentations, disclosure requirements, and the systems supporting such requirements. Yet, despite the similarity of their contents, the impact of the CTR and the MDR on their respective industries are very different. One reason for this disparity is the large number and diversity of medical technology products that may have hindered previous efforts in the regulatory process harmonisation.[7] There are approximately 500,000 medical technology products in Europe.[12] According to Boumans, "on average, more new medical devices enter the European market in a single day than new medicines in a year."[3] Another reason is that not only were the regulatory pathways for the two groups of products very different previously, the regulatory requirements in earlier legislations were clearly more stringent for medicinal products than for medical devices.[13] With the passing of the CTR and the MDR, these requirements have been brought to the same level of stringency. Thus, the difference in the impact on the two industries is due to the different baselines – the Directives – and the change in requirements that the new regulations brought with them (Table 2). For those who believe in the two parallel universes configuration, applying the rules governing medicinal products to devices was almost a quantum leap into regulatory space.

Are they really that different?

At first glance, medicinal products and medical devices are indeed like "different species". There are inherent differences in their appearance, mechanisms of action, product development

Table 2. The impact of new regulations on the pharmaceutical and medical device industries

	Medicinal Products			**Medical Devices**		
	Directive[1] 2001/20/EC + Paediatric Regulation 1901/2006 (Baseline)	**Regulation[2] 536/2014 (CTR)**	**Δ[3] and impact[4] on pharma industry**	**Directives[1] 93/42/EEC and 90/385/EEC (Baseline)**	**Regulation[2] 2017/745 (MDR)**	**Δ[3] and impact[4] on medical device industry**
Clinical study conduct	Mandatory	Similar requirements, new application process	Small Δ Low to moderate impact (mainly timelines)	Not clearly required when following "equivalence" route	Mandatory for most device classes	Large Δ High impact
Clinical study documents	Mandatory	Similar requirements; more documents to disclose	Small Δ Low to moderate impact	Required but not clearly structured	Mandatory, with document requirements similar to pharma	Small Δ High impact
Clinical trial registration	Mandatory	Mandatory	Small Δ Low impact	Not required	Mandatory	Large Δ High impact
Clinical trial results disclosure	Partial disclosure required	Full disclosure mandatory	Large Δ Moderate to high impact	Not required	Full disclosure mandatory	Large Δ High impact

1 Directive: A "directive" is a legislative act that sets out a goal that all EU countries must achieve. Individual countries devise their own laws to reach these goals.
2 Regulation: A "regulation" is a harmonised legislative act that must be applied in its entirety across the EU member states.
3 Δ: Change from baseline (i.e., Directives and Paediatric Regulation 1901/2006).
Low Δ: no or minimal change in requirements; Large Δ: new requirements, substantial changes to previous requirements.
4 Impact is arbitrarily rated as low, moderate, or high, based on Δ and authors' regulatory experience with the previous and new requirements.

process, and life cycles. But they also have much in common. They are products used as medical interventions in human patients. They have a medical purpose, i.e., to cure a disease, treat a condition or control and alleviate symptoms and pain. And their effectiveness and safety need to be demonstrated in clinical trials or investigations. It follows that the CTR and the MDR are also not so different after all, and a comparison of their requirements for clinical trials and investigations supports this inference (Table 1).

Both the pharmaceutical and medical device industries have had their share of efficacy scandals and safety mishaps.[13] The lessons learned from such events have been used to refine regulatory requirements that should prevent the same mistakes from happening again. In the era of patient centricity, the type of product considered – be it medicinal product or medical device– does not really matter. The benefits and the risks to the patients through patient-focused medical care are of upmost importance, regardless of which universe they belong to.

It is likely that the transition to merge the two universes of medicinal products and medical devices will take some time. Nonetheless, the alignment of the CTR and the MDR requirements is paving the way in the direction of a single universe.

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Disclaimers

The opinions expressed in this article are the authors' own and not necessarily shared by their employers or EMWA.

Conflicts of interest

Raquel Billiones is an employee of a pharmaceutical company. Kathy B. Thomas is an independent consultant to pharmaceutical industry on matters concerning clinical trial disclosure. The authors have no other conflicts of interest to declare.

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