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Medical Device Regulation from a Health Service Provider's Perspective

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Abstract: Unfamiliarity with medical device regulations can sometimes be a barrier to deploying technology in a clinical setting for researchers and innovators. Health service providers recognise that innovation can happen within smaller organisations, where regulatory support may be limited. This article sets out to increase transparency and outline key considerations on medical device regulations from a UK healthcare provider's perspective. The framework used by Guy's and St Thomas' NHS Foundation Trust (GSTFT) for assessing research devices is presented to give an overview of the routes that R&D medical devices take to enter a clinical setting. Furthermore, current trends on research studies involving medical devices were extracted from the GSTFT internal R&D database and presented as the following categories (i) commercial vs. non-commercial, (ii) assessment type and (iii) software vs. non-software. New medical devices legislation will be introduced within the UK in July 2023. It is anticipated regulating software as a medical device may become more challenging for healthcare providers and device manufacturers alike. It is therefore important for different stakeholders involved to work together to ensure this does not become a barrier to innovation.

Keywords: medical device regulations; healthcare provider; software as medical device; technology translation; quality management system

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1. Introduction

Innovation can often happen at the level of a research organization or by an early–stage innovator. Development of medical devices may require extensive clinical investigation and evaluation to ensure patient safety. Navigating the path towards clinical investigation and evaluation could pose a barrier to early–stage innovators and hence may impede innovation. The aim of this article is to give early–stage researchers and innovators an overview of the regulatory environment in the UK from a healthcare provider's perspective, and possible routes for R&D medical devices to enter testing in a clinical setting.

In the UK, medical devices are regulated under the Medical Devices Regulations 2002 (commonly referred to as the UK MDR 2002). This legislation implemented existing EU medical devices directives into UK law. The legislation required CE marking for all medical devices sold within the UK, to indicate compliance with EU legislation. The most widely applicable of the EU directives is the Medical Devices Directive (Directive 93/42/EEC, commonly referred to as the MDD) [1]. The legal requirements for medical device manufacturers are largely contained within the MDD, with some UK specific requirements contained within the UK Medical Device Regulations 2002 [2].

The MDD is no longer in force within the EU, having been replaced by the EU Medical Devices Regulation (2017/745, commonly referred to as the MDR) [3], on the 26 May 2021. New medical devices legislation will be introduced within the UK in July 2023, the contents of the new legislation are not known but may have similarities to the EU MDR.

Alongside the MDD, the UK Medical Devices Regulations 2002 implemented two other EU directives into UK law; the Active Implantable Medical Devices Directive

(AIMDD, 90/385/EEC) [4] and the In Vitro Diagnostic Medical Devices Directive (IVDD, 98/79/EEC) [5]. Within the UK, the legal requirements for these devices remain largely contained within the EU directives. Within the EU the IVDD remains in force. The AIMDD has now been withdrawn, with the requirements for active implantable medical devices now contained within the MDR.

2. Role as a Gatekeeper for Medical Devices

Healthcare providers in the UK have a statutory responsibility to ensure patient safety. Most health providers have a process for approving and accepting medical devices for local deployment. Clinical engineers will often act as gatekeepers, assessing and approving new medical devices/devices being used for research. As an example to help improve transparency, the framework used by the Guy's and St Thomas' NHS Foundation Trust (GSTFT) for assessing research devices is presented below.

There are several possible routes for R&D devices to enter a health service, these are broadly categorized into: (i) Commercial R&D, (ii) Non-commercial R&D and (iii) Non-R&D. Each of these categories will be described in more detail in the rest of this section. It is important to note that ethics approval is required for medical device research involving patients.

2.1. Commercial R&D

The sponsor of commercial R&D studies is typically a commercial body, usually either a medical devices manufacturer or a pharmaceutical company. Clinical engineers are involved in the assessment of any study which involves medical devices, irrespective of who the sponsor is.

Studies run by pharmaceutical companies may involve medical devices. These studies do not typically assess the medical devices themselves; these devices are ancillary, for instance diagnostic devices may be used to assess treatment outcomes. In these cases, the devices used are post-market, with pre-existing regulatory approval. Clinical engineers' involvement in the assessment of these studies is typically limited to checking that devices do carry the necessary regulatory approval (i.e., UKCA or CE marking) and are used within their intended purpose.

Studies run by medical device manufacturers are more likely to assess the performance of medical devices themselves. These studies may involve pre-market or post-market devices. Even studies of pre-market devices typically involve devices whose designs are fairly mature.

Trusts typically charge more for commercial studies than non-commercial ones and retain less ownership of the data produced by the study.

2.2. Non-Commercial R&D

The sponsor of non-commercial studies is typically a non-commercial body, often the NHS Trust itself, or a university. These studies are very diverse. Non-commercial R&D studies which have a medical device as the subject of the study can involve early–stage technologies whose designs are less mature than those typical of commercial pre-market evaluations.

Trusts typically charge less for non-commercial studies than commercial ones but will have stricter contractual limitations governing what data can be shared with the sponsor.

2.3. Non R&D

In some cases, new medical devices, medical device modifications, or systems of medical devices are not for research purposes, they are to meet an identified clinical need within the Trust. Devices we have seen within GSTFT include fixation devices to minimise patient movement during imaging, and incubator trolleys mounting multiple devices which require mitigations to assure electrical safety.

3. Internal Assessment Considerations

Clinical engineers involved in the assessment of medical devices for deployment within their local institution must consider several factors. Their ultimate responsibilities are to ensure that any deployment is safe and does not adversely affect the patient care delivered by their organisation. However, the assessment questions are also driven by the regulatory route used for the deployment, and local policies and norms.

Regulatory approval provides a high degree of assurance of device safety and performance. A correspondingly light assessment is therefore required for these devices.

Where a study has been notified to the Medicines and Healthcare products Regulatory Agency (MHRA), and they have indicated that they have no concerns, this too provides a high degree of assurance and reduces the scope of the assessment required from local clinical engineers.

No such assurance exists for medical devices which do not have regulatory approval, and where studies have not been notified to the MHRA. Deployment of these devices is permitted in a limited range of specific circumstances. Assessments of these deployments include detailed technical assessments, together with a consideration of the legal deployment route.

4. Approval and Assessment Type

Based on the above factors mentioned, the decision pathway to ensure patient safety could be categorised into the following assessment types: (i) Trust owned medical devices, (ii) UKCA/CE marked devices, (ii) registered clinical investigations, (iii) basic safety assessments and (iv) Health Institute Exemption.

4.1. Trust Owned Medical Devices

Some researchers wish to use medical devices which are already in clinical use at a Trust for their research. Provided that the devices are not being modified or used for a novel purpose, there are no regulatory barriers to this use.

4.2. UKCA/CE Marked Medical Devices

It is very common for research studies to involve use of medical devices which are UKCA/CE marked and available for purchase. There are no further regulatory requirements to this type of use. However, individual Trusts may have local governance arrangements which determine which medical devices may be introduced to the Trust. New devices may have to meet local governance requirements before they may be introduced to clinical areas.

4.3. Registered Clinical Investigations

To demonstrate that their device conforms to the regulatory requirements, manufacturers must sometimes run clinical studies known as *clinical investigations*. In many respects these are the medical devices equivalent of a clinical trial of an investigation medicinal product (CTIMP). Within the UK, the MHRA must be notified of any clinical investigation and have the opportunity to object before it may proceed.

Clinical investigations are typically run as commercial R&D projects within NHS Trusts. Once the MHRA have indicated that they do not object, Trusts are usually happy for the device to be used with their patients, subject to the usual R&D governance requirements.

This is a common but resource intensive route for devices to enter a NHS Trust, the manufacturer may act as the sponsor of the clinical investigation. This will commonly involve dedicated regulatory experts and clinical trials units. Securing funding for this step is a common barrier for devices undergoing the innovation translation process.

4.4. Basic Safety Assessments

In some cases it is possible for an investigational medical device to be used within a clinical study without being used for any medical purpose. For example, a diagnostic

device may be used to make clinical measurements which are used for research purposes (e.g., for comparison with measurements made by a gold standard technology) but are not used for any clinical purpose (i.e., they are not used by clinicians to make decisions about patients' care).

Existing medical devices legislation applies only to devices intended by their manufacturer to be used for medical purposes. Investigational devices which are not intended to be used in this way do not need to comply with these legislative requirements. Healthcare providers are nonetheless required to ensure that such devices are safe for use with patients and will often wish to perform a "basic safety assessment" for these devices.

Clinical medical devices research conducted under a basic safety assessment can be a good option for studies involving medical devices whose design is not yet mature, and which can be meaningfully assessed without impacting patients' clinical care. However, data from these studies cannot typically be used to demonstrate devices' safety or performance as part of a formal conformity assessment process. A clinical investigation, notified to the MHRA, is required where research outputs are intended to be used in this way.

Basic safety assessments are also sometimes used to ensure the safety of non-medical devices which are introduced to clinical areas as part of a clinical study.

4.5. Health Institute Exemption

Within the EU, the MDR has introduced new requirements for healthcare institutions who wish to manufacture and use medical devices internally. These requirements are more demanding for healthcare providers than those under the previous legislation. There are requirements to be more structured and transparent, such as for health institution to draw up publicly available declaration that the devices meet the general safety and performance requirements. Most notably in the MDR there is now a specific requirement for an appropriate quality management systems. This will require that health institutions adapt their existing quality management system as they adopt new technology that is developed and manufactured in-house.

It is important to note that at the time of writing, the MDR does not apply in the UK. However, it is prudent for researchers developing medical devices to consider the quality management system requirements early. There is a need to make such systems more widely available to research institutions and harmonised with partnering healthcare providers.

5. Current Trends of R&D Devices

GSTFT is the largest NHS Trust in the UK. It has a well-established research partnership with King's College London, as part of the King's Health Partnership. It is therefore a very research active centre. The following summarises some key statistics extracted from our internal database of R&D device research activity between 2019 and 2021.

Table 1 presents the proportion of commercial and non-commercial clinical research and Table 2 presents the proportions of the different types of assessments conducted in 2019. Figures from January–December 2019 were chosen, as they represent the 12 months leading up to the start of the COVID-19 pandemic and may be informative of the amount of research activity that would occur when there were no disruption of the service.

Table 1. Percentage and number of studies GSTFT received in 2019 via commercial and non-commercial routes.

Route to Healthcare Providers	% (Number of Studies)
Commercial	33% (27)
Non-commercial	60% (49)
Non-R & D	7% (6)

Table 2. Percentage and number of studies GSTFT received in 2019 under different assessment types.

Assessment Type	% (Number of Studies)
Trust owned medical devices	2% (2)
CE marked medical devices	45% (37)
Registered clinical investigations	4% (3)
Basic safety assessments	31% (21)
Health Institute Exemption	7% (5)

The MDD included software under the "active device" category after an amendment made in 2007, software as a medical device is covered and can be classified. New legislation outlined in the MDR, however, prescribed a more robust and specific approach to regulating software as medical devices.

This change could present a particular challenge for healthcare providers because there are likely to be many non-R&D software algorithms (e.g., spreadsheet algorithms) which require more rigorous governance under the new legislation. This type of non-R&D software algorithm will likely fall in the HIE category. The MDR has many more requirements for healthcare providers who wish to use the HIE than does the MDD.

Table 3 presents the number of research projects that involved software vs. non-software. The proportion of studies classified as software was low in 2019. If new medical devices legislation in the UK mirrors the EU MDR then the number of medical device software assessments are anticipated to rise as non-R&D algorithms are brought into compliance with the new legislation.

Table 3. Percentage and number of studies GSTFT received in 2019 grouped under software vs. non-software.

Software vs. Non-Software	% (Number of Studies)
Software	4% (4)
Non-software	96% (104)

Figure 1 shows the number of studies received via the commercial and non-commercial routes since Jan-19. There is generally less commercial research activity than non-commercial, but non-commercial research activity is the more variable. All research activity stopped during the first peak of COVID-19 pandemic and levels have been very erratic since then, particularly for non-commercial research.

6. Discussion

Healthcare providers are aware that innovation is key to improving healthcare. Medical device innovation may occur at an innovator or research organization level, where routes to clinical deployment for research may pose a hurdle. This article has discussed the various pathways which exist within an NHS Trust and has discussed the range of research types supported by healthcare providers.

With the introduction of new medical device legislation in Europe, and new legislation also on the horizon for the UK, this article aims to increase transparency over healthcare providers' considerations when approving a piece of medical device for clinical studies. The largest change in terms of the device approval from a healthcare provider's perspective will likely be the increased requirements for deployments under the HIE. This imposes on the healthcare provider a similar responsibility to a commercial manufacturer, such as a more specific process governance with a quality management system. This may require adaptation of processes when introducing a newly developed in-house technology. From manufacturers' points of view, it is likely that the tighter classification rules and conformity assessment routes will pose a challenge. Transparency and cross-learning here is important as Trusts and healthcare providers will each have new responsibilities to ensure all software complies with the new legislation requirements.

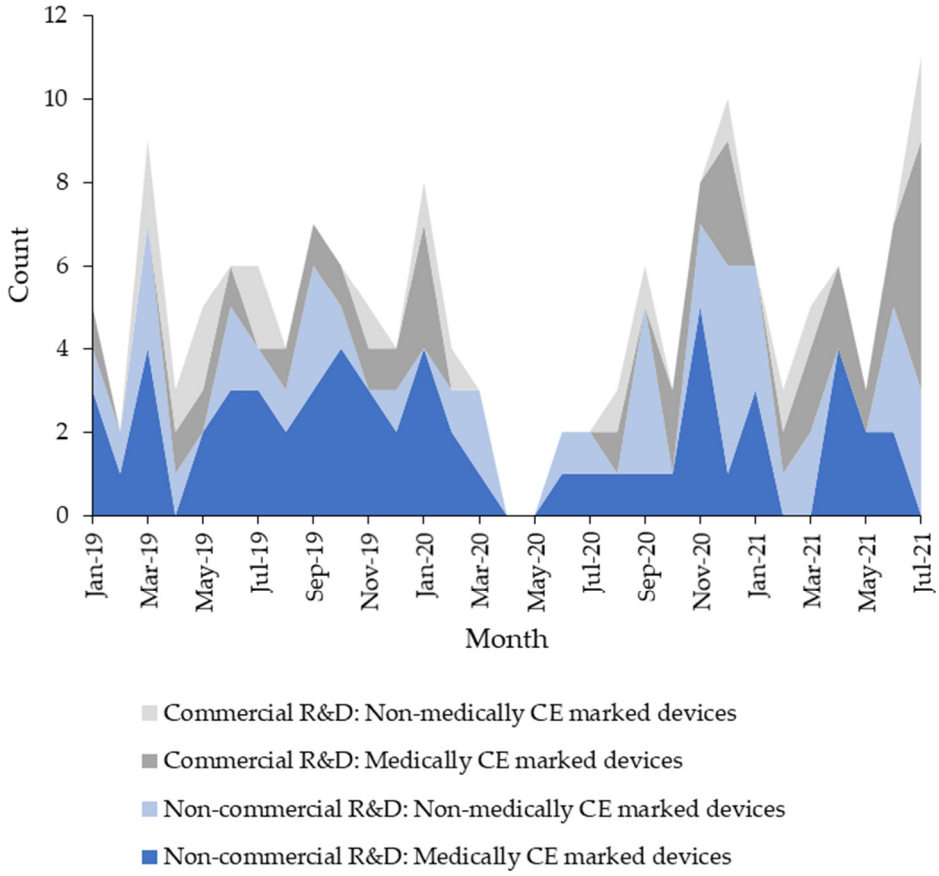

Figure 1. Volume of research studies involving medical devices assessed by GSTFT received in 2019–2021.

The volume of clinical studies is likely to rise in the future as the healthcare demand created by the COVID-19 pandemic falls. Research activity is returning to pre-pandemic levels and may soon exceed historic levels as Trusts begin clearing the backlog of research studies delayed by the pandemic, and with the additional research opportunities created by the pandemic.

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References

1. European Council Directive 93/42/EEC of 14 June 1993 Concerning Medical Devices. *Off. J. Eur. Union L* **1993**, *169*, 1–43.
2. Secretary of State. The Medical Devices Regulations 2002, No. 618, UK Statutory Instruments.
3. European Union. Regulations (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices. *Off. J. Eur. Union L* **2017**, *117*, 1–175.
4. Council Directive 90/385/EEC of 20 June 1990 on the Approximation of the Laws of the Member States Relating to Active Implantable Medical Devices. *Off. J. Eur. Union L* **1990**, *189*, 17–36.
5. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices. *Off. J. Eur. Union L* **1998**, *331*, 1–37.