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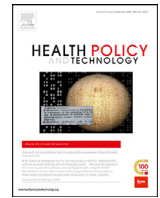
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Original Article/Research

A multidisciplinary approach to online support for device research translation: regulatory change and clinical engagement

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ABSTRACT

Objectives: To promote an appreciation of the EU medical device regulatory framework in the biomedical research community and encourage greater levels of clinical engagement to further medical device research innovation, translation and effective clinical trials.

Methods: An interdisciplinary, iterative, needs-based design approach was used to develop medical device regulatory training, information and clinical expertise resources.

Results: A multimedia based self-paced e-Learning course focusing on the 'Fundamentals of Medical Device Design and Regulation' was produced in tandem with an interactive online web portal: Medtech Translate.

Conclusions: Health research translation relies on both clinical input and regulation to drive progress and to ensure quality and safety standards from concept development to clinical investigation. A lack of regulatory awareness and access to clinical expertise has the potential to significantly impact on health research translation and ambition for market. Our interdisciplinary academic-regulator-clinical-industry led approach meets the need for a coordinated stakeholder response to support innovation and promote growth in the medical technology sector.

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Introduction

Regulation functions to protect public health and to provide stability in the marketplace by ensuring delivery of safe, high quality medical devices for clinical use across the European Union (EU). In Europe the Medtech industry employs over 675,000 people directly and accounts for some 27,000+ companies [1]. Ireland figures prominently in this sector, with 9 of the world's top 10

Medtech companies based there. Ireland has the highest number of personnel per capita employed in healthcare technology in the EU, and is ranked the second largest exporter of medical devices in the same jurisdiction with national output accounting for as much as 75% of global orthopaedic knee joint production and 80% of cardiovascular stent production [2]. With the EU medical device market comprising some half million devices, their variation in complexity, risk profile and application makes the implementation and enforcement of harmonised regulation across EU member states an important and challenging task.

The EU Medical Device and *In Vitro* Diagnostic Regulations (EUDR) [3,4] were first published in 2017 with a view to addressing

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the many regulatory challenges observed in such a diverse market where safety, consistency of performance and risk control are of paramount importance. On full application the EUDR will supersede the existing Medical Device Directives; being broader in scope with greater numbers of products (including devices manufactured within hospitals) subject to their requirements and placing greater emphasis on quality management system implementation. They also involve device classification changes (IVD devices in particular) and increase requirements for in-house regulatory expertise and pre- and post-market clinical data generation. The official date of application of the Medical Device Regulations is May 2021. This is a year later than originally planned with the delay being primarily to allow regulatory agencies, authorities and manufacturers to attend to Covid-19 related concerns. The 2022 date of application for the *In Vitro* Diagnostic Regulations to date remains unchanged.

The main objectives of the EUDR are to strengthen and develop the existing regulatory system for medical devices, to increase consistency within the system, increase the oversight on the highest risk medical devices and increase transparency. However, the EUDR also have enormous potential to impact on device development processes and commercial competitiveness in the sector by significantly changing device innovation and business practices [5]. At all stages of the device development process the implementation of the EUDR will demand greater clinical input to meet the increased requirement for proof of clinical safety and performance. In contrast to the Directives, the Regulations require, for certification purposes, the generation of greater amounts of clinical data for the specific device rather than relying on data from equivalent devices [6]. In addition, the obligations for more robust post-market surveillance systems, post-market clinical follow up in particular, are described within the new Regulations. This is particularly true for IVDs for which there is a requirement to show, not only that the test is valid, but also that it is necessary for making a treatment decision that will affect patient outcomes [6]. Therefore, effective, informed navigation of the regulatory framework by health researchers is vital to facilitate the future translation of innovative medical devices from concept to clinical application. Innovation of new technologies affords patients and health systems access to new diagnostic and therapeutic options. Significantly, however, in its Horizon 2020 Coordination and Support Action, the EU identifies a lack of regulatory science in medical teaching and training programmes as 1. the reason for diminished capacity amongst researchers to incorporate a regulatory approach to research translation, and 2. a significant barrier to patient access to state-of-the-art healthcare [7].

From an economic viewpoint continuous innovation and translation of biomedical research is vital for the ongoing success of the Medtech industry in Europe and to the Irish economy. Research led innovation and academic partnership has been recognised as key to improving rates of health technology innovation. Consequently, a growing need for industry to be part of an integrated ecosystem comprising academia supported by national enterprise strategies focusing on successful commercialisation and reduced times to market has been identified [8]. By increasing clinical involvement from the earliest stages of academic research, a more practical approach to 'disruptive' device development can be driven from a basic research level to advance healthcare. Such an approach can make best use of limited resources and produce targeted, effective devices [9]. Importantly, from this perspective, in Ireland the sector spans some 450 companies with 68% of those involved in R&D [10]. Key to Ireland's success has been the level of active collaboration in industry with some 25% of companies having a shared services mandate and with many of them fostering close linkages with national academic centres of excellence. It is a stated objective of the Irish Government that 'education and training providers

place a stronger focus on providing skills development opportunities that are relevant to the needs of learners, society and the economy' [11,12].

In this context, and being particularly mindful of the changing regulatory infrastructure in Europe and the recognised need for greater levels of clinical involvement in device innovation, Clinical Research Development Ireland, a research partnership supporting biomedical research translation in leading Irish Universities, in collaboration with CÚRAM, the Science Foundation Ireland (SFI) Research Centre for Medical Devices have sought to firstly, address the lack of medical device regulatory knowledge and training amongst our target audience (clinician scientists, biomedical researchers and small / medium enterprises (with early stage innovation projects)); and secondly, facilitate more active clinical engagement to support innovation and clinical trials.

In collaboration with strategically chosen stakeholders to include the national regulatory agency, national standards authority, representation from industry and the national clinical research infrastructure our primary objective was to develop online regulatory training tools focused towards our target audience coupled with a web based regulatory information portal underpinned by a device development clinical support function. Greater understanding as to how to navigate the regulatory system and its requirements in the biomedical research community is key to advancing healthcare innovation nationally and Europe-wide. A coordinated approach to the gathering and provision of such expertise and knowledge is central to serving this need.

Methods

The primary objectives of this work were twofold: 1. to make positive changes to the state of regulatory knowledge in the field; and 2. to support clinical involvement throughout the life cycle of device development. To realise these aims a joint needs-based design and development approach, supported by strategic stakeholder engagement, was taken to support project resource development (Figure 1) [13].

Interdisciplinary infrastructure

Project objectives are underpinned by an interdisciplinary collaborative framework, managed by Clinical Research Development Ireland (CRDI), in partnership with CÚRAM, the Science Foundation Ireland (SFI) research centre for medical devices. CRDI is a not-for-profit partnership comprising five academic institutions with a focus on advancing patient care and health service delivery through clinical and translational research. CRDI's remit includes the provision of education programmes and information resources developed by engaging with the national and international research community and harnessing cross-institutional academic, clinical, and industry expertise. CÚRAM, with a remit to further 'smart medical device' innovation to treat global chronic diseases, comprises 9 academic research partners and a strong portfolio of collaborative medical device research activity involving some 28 industry partners. The value of the CRDI / CÚRAM partnership to the realisation of project ambitions lies in its capacity to foster and sustain linkages between principal actors in relevant sectors (clinical scientists, academia and industry) and, by their natures, both act as natural conduits to target audiences. Previously we analysed how the introduction of the EUDR will affect the biomedical research translation capability of CÚRAM, as well as the Medtech sector in Ireland and Europe [5]. Based on this sector analysis, we have developed innovative researcher training and research support resources in association with industry, regulatory collaborators and the clinical research infrastructure (Figure 2).

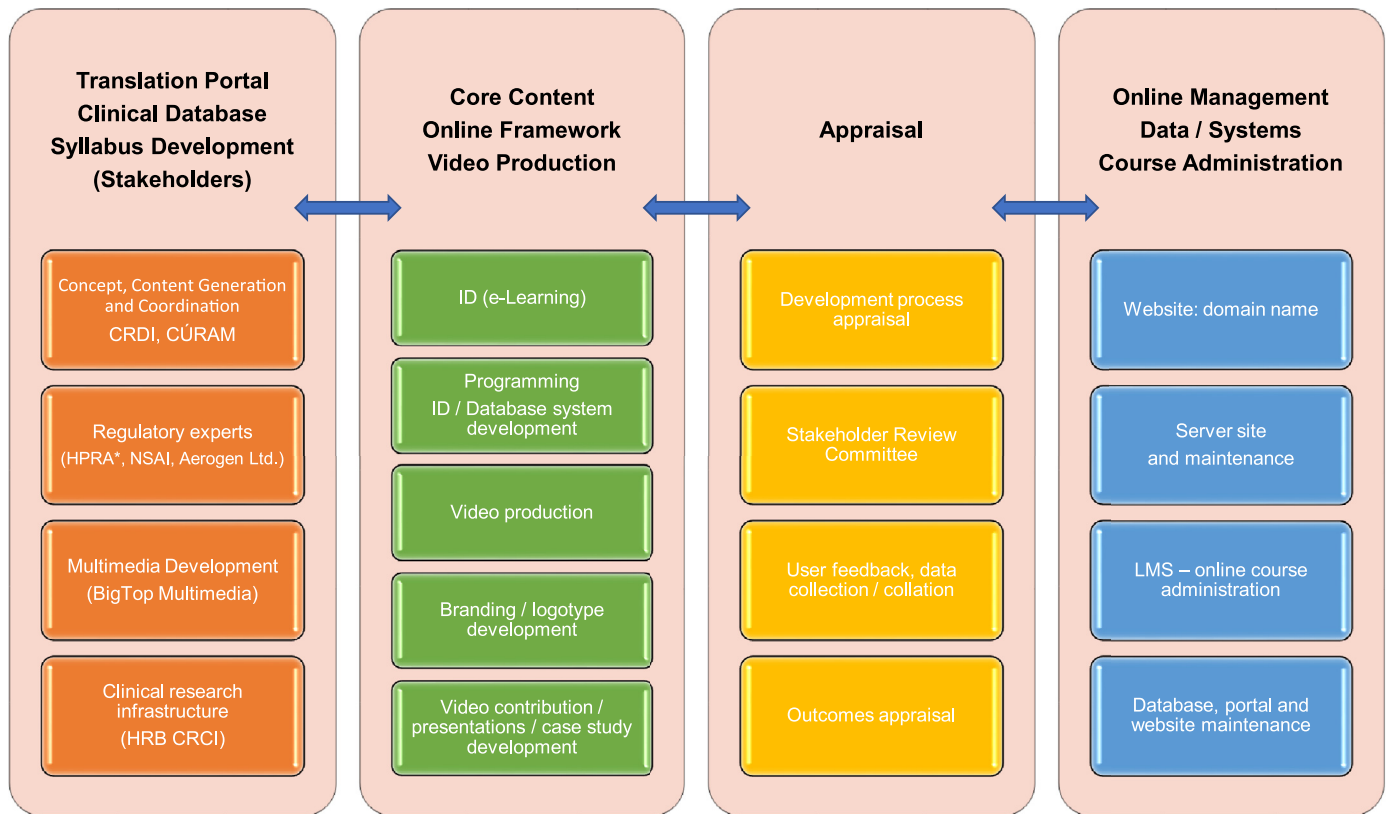


Figure 1. Collaborative iterative development process (personnel / organisations / resources) of needs driven approach to online regulatory training, information and guidance resource development program. Adapted from: Stotz S, Lee JS. J Nutr Educ Behav. 2018 Jan; 50(1): 90 – 95. Health Products Regulatory Authority: HPRA; National Standards Authority of Ireland: NSAI; Learning Management System: LMS; Instructional Design: ID. * Advisory role but not content validation.

Interdisciplinary Collaboration

Regulatory agencies, Industry, Clinical Research, Clinicians, Multimedia

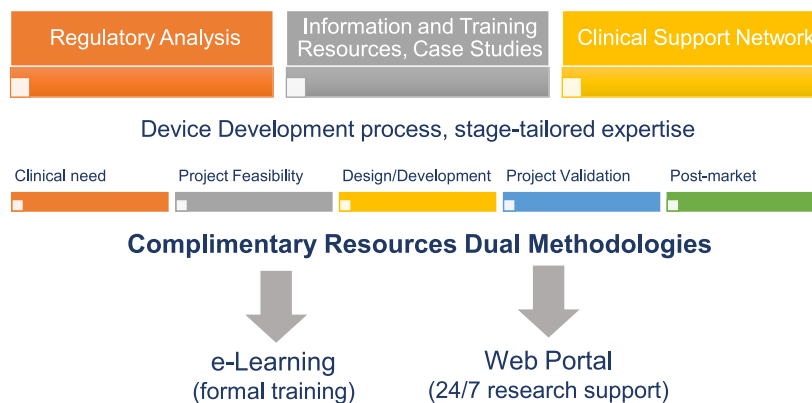


Figure 2. Collaborative stakeholder engagement and project resources used to underpin and inform the design and development of e-Learning and online information and training resources, the Medtech Translate portal and clinician database.

Regulatory expertise

Regulatory expertise is provided by the Irish national competent authority, the Health Products Regulatory Authority (HPRA) and the National Standards Authority of Ireland (NSAI). The NSAI, a designated notified body, is responsible for the assessment of conformity of medical devices and in-vitro diagnostic medical devices to the applicable EU medical device regulatory legislation as part of the pre-market approvals, or CE marking process. The HPRA, as the national designating authority, is responsible for the surveillance and control of the performance and activities of notified bod-

ies operating within its remit as well as the market surveillance of approved devices to ensure that they are safe, perform as intended and do not pose an unnecessary risk to public health. The HPRA is also responsible for reviewing and approving applications to conduct clinical investigations (research) of medical devices in Ireland. Both agencies support the goals of this partnership by providing oversight of training content and by contributing to the development of project resources, including case study videos describing the conformance assessment process for CE marking from the perspective of the notified body.

Industry engagement

Aerogen Ltd., a world leading aerosol drug delivery company develops nebulisers for use in diverse clinical settings. In its business and innovation practices Aerogen focuses strongly on research translation to ensure that its technology remains state-of-the-art. For this reason we partnered with Aerogen Ltd. to generate educational video case studies aimed at explaining to our target audiences, from the manufacturer's perspective, how the medical device regulatory framework influences research translation and is applied to manufacturing and business processes. These case studies also reflect on the potential for the EUDR to impact on existing and future product generation.

Clinical research infrastructure

Project objectives are supported by HRB Clinical Research Co-ordination Ireland (HRB CRCI), an integrated clinical research network offering centralised support and expertise to enable collaborative trials nationally through the harnessing of the constituent infrastructure and resources of its affiliate clinical research centres/facilities. Together, the CRDI / CÚRAM partnership and HRB CRCI seek to drive the translation of clinically focused device research by investing in the development and delivery of innovative device-related training and information resources and in the facilitation of clinical involvement in device development and trials.

Multimedia development

e-Learning and web portal development and delivery were undertaken by BigTop Multimedia, a design, web and mobile application development company. Input included guidance on instructional design, e-Learning and portal web framework development, devising methods for content delivery; artwork development, videography and post-development technical support as required. Design and development platforms included Moodle, Invision and Adobe XD v. 16.0.2.8 for e-Learning and portal respectively with the portal being delivered on the WordPress 5 platform. Videography, post production and distribution was supported using Vimeo Pro. Online learning requirements which include course enrolment and administration, file management, examination management and outcome reporting is coordinated through Moodle with web portal analytics being supported by Google Analytics.

Results

e-Learning

e-Learning is a useful tool to provide a subject matter-focused, flexible and easily accessed knowledge base to support clinical research and career development [14,15]. In collaboration with partnership stakeholders, we produced a bespoke online e-Learning course, comprising 2 modules, focusing on the 'Fundamentals of Medical Device Design and Regulation (FMDDR)'.

FMDDR was designed to deliver regulatory knowledge in the context of medical device design and development. It comprises two modules, each devised using different methodological approaches yet both delivering multimedia based, self-paced blended learning supported by web-accessible resources. The purpose of using differing delivery methodologies was three-fold: 1. to reflect and complement complement the divergent subject matter; 2. to utilise access to contributor expertise as effectively and efficiently as possible; and 3, the differing styles of both modules will act as methodological test cases to assess user learning preferences to inform future e-Learning development and existing module updates.

The first module, 'Principles of Medical Device Design (PMDD)' describes how the disciplines of engineering and life sciences combine during medical device design and development. Content generation was academic led and aimed to convey the multi- and inter-disciplinary nature of the field as well as speaking to key concepts such as biocompatibility and biomaterial / biomechanical processes. PMDD content generation involved identifying and gaining support from internationally recognised medical device researchers, based in CÚRAM and elsewhere in Europe. In all 9 experts contributed to the course content; 1 industry based, 4 from National University of Ireland, Galway with 4 from universities in Italy, the United Kingdom and Switzerland. Contributor competencies include tissue engineering, therapeutic angiogenesis, regenerative medicine, design by self-assembly, the neural-device interface (nanotubes) and orthopaedic implantation. Each contributor developed course content based on their area of expertise to include face-to-camera pieces to support the production of video lectures. They also provided course resources to include relevant reading lists and examination material.

In addition to core design and development content PMDD also covers more holistic aspects of medical device design including future design and development strategies, the device translation process (how devices are tested and transformed for therapeutic effectiveness and market), the process of assessment of clinical need/market identification, the selection of optimal treatment strategies and the identification of design factors needed for particular clinical applications.

The second FMDDR module 'EU Regulation of Medical Devices (EURMD)' was formulated using the 'ADDIE' instructional design model (Figure 3) which supports a systematic iterative needs-focused method of knowledge delivery for specified audiences [16]. Content development in this instance required examination of the existing parameters of the EU regulatory framework, the key features of the EUDR, and the multivariate reasons for the change in legislation.

As such, in addition to referring to published statutory documents [3,4,17,18], a number of relevant data sources devised by entities including the EU Commission, the National Competent Authority and industry representative bodies were reviewed to support content generation. They describe a. the medical device legislative framework under the Directives and Regulations; b. the reasons and need for regulatory change, and c. the potential impact of increased regulation on the sector [19–22].

The subsequent refinement and reduction of the initial regulatory content (reflecting the Medical Device Directives) was executed iteratively by means of several review and feedback sessions involving the Health Products Regulatory Authority and National Standards Authority of Ireland. This resulted in the apportioning of subject matter themes into discrete topics with a view to conveying complex regulatory concepts at a pace and level suitable for intended audiences.

In the 3rd year of FMDDR delivery, in recognition of the impending full application of the EUDR, we reviewed and updated, in collaboration with NSAI and HRB CRCI, EURMD's regulatory content to reflect the requirements of the new legislation. We also, subsequently, engaged an external consultant to conduct an appraisal of the revised course material. To further reinforce this review and validation process we also sought the input of 9 representatives of our target audience; to include PhD and Post-doctoral researchers, early stage device developers and representatives of innovation support agencies. Specifically, they were asked to review the quality and approach to delivering the regulatory material in the context of the development of the project's web portal but their responses also served to inform the approach to the re-examination of the e-Learning material.

Analysis	Outcomes / Actions / Activities
Identify target audience	Biomedical researchers in academia, academic spin-out companies, SMEs
Identify knowledge and skills gaps	Greater understanding of the EU medical device regulatory system amongst biomedical researchers; greater clinical engagement in device development and research translation activities
Delineate course content and requirements	EU medical device regulatory framework and requirements for CE marking (in 7 sub sections); digest and abridge subject matter for intended audience
Design	Outcomes / Actions / Activities
Establish the learning objectives	An ability to understand and describe the EU medical device regulatory framework and its requirements for device authorisation for market
Instructional Design approach	Blended learning approach comprising interactive e-Learning supported by expert led workshops
Delivery and evaluation method	e-Learning delivery which reinforces effort and involves student self-testing on a section by section basis; evaluation by online MCQ examination
Development	Outcomes / Actions / Activities
Content planning & generation	Pertinent content identified in collaboration with subject matter experts
Videography	Content iteratively developed to support proposed delivery style and methods
Programming	Identify content delivery approach with input from the multimedia developer using ADDIE instructional design principles
Learning platform	Choose online learning platform and course management system
Implementation	Outcomes / Actions / Activities
Accreditation	Appoint University coordinator; attain university (ECTS) accreditation
Course roll out	Develop Open Badge for acknowledgement of continuous professional development; identify subject matter experts for workshop development and delivery
Higher Education Institution and online course administration	Establish online course administration / examination system; appoint coordinator/tech support
Evaluation	Outcomes / Actions / Activities
Iterative stakeholder review; end user review; learnings for improvement	Develop online surveys to examine participant reactions to, and satisfaction with: <ul style="list-style-type: none"> ➤ the content delivery approach of both modules; ➤ the relevance of each module's content to audience's needs; Executed to inform course improvement objectives for subsequent deliveries

Figure 3. ADDIE e-Learning structure with corresponding outline of planned EURMD module design, development, implementation and evaluation activities. Adapted from: Ghiardini B. E-learning methodologies: A guide for designing and developing e-learning courses [Internet]. [cited 2018 June 06] Available from: <http://www.fao.org/docrep/015/i2516e/i2516e.pdf>. European Union: EU; Small and medium enterprises: SMEs; multiple choice question: MCQ; Analysis, Design, Development, Implementation, and Evaluation: ADDIE; European Credit Transfer Accumulation System: ECTS.

In the case of both modules (PMDD and EURMD), successful completion of course requirements involves module specific online multiple choice question examination and participation in interactive problem-solving workshops formulated to examine representative examples of research focused device development projects delivered by medical device research, industry and regulatory experts.

e-Learning impact and reach

Year 1 and 2 FMDDR participants (54% response rate) were surveyed as to their impressions of the course and were asked to rate their responses from 1 (totally disagree) – 5 (totally agree). Re-

spondents were very positive regarding the approach to content delivery and indicated strongly that the 'EU Regulation of Medical Devices' module made a positive contribution to their understanding of the field (Table 1).

Also, importantly, 94% of total respondents (2017 – 2019) rated the overall FMDDR course as good to excellent. Since its inaugural year FMDDR has seen a 2-fold increase in participation and a similar increase in the number of higher education institutions and other organisations represented among course entrants [23]. Course alumni, which now number 93, are predominantly drawn from national higher level academic institutions and are of varying biomedical, bioengineering, clinical academic and, to a lesser extent (<9%) industry/other backgrounds (Figure 4 (a, b)).

Table 1

Outcomes (average ratings) to the end of year Fundamentals in Medical Device Design and Regulation feedback form (2017 – 2019). As part of this review participants (54% response rate) were surveyed as to their impressions of the EURMD module and were asked to rate their responses from 1 (totally disagree) – 5 (totally agree). Significantly the majority of respondents indicated that the module fulfilled its brief in that it added to their understanding of the EU medical device regulatory framework (4.6 average rating). EU Regulation of Medical Devices module: EURMD.

Question	Average rating (2017–2019)
1. the content of EURMD was clear and easy to understand?	4
2. the content of the EURMD module followed a logical order?	4.5
3. the amount of information and work contained in the module was reasonable?	4.3
4. EURMD contributed to my knowledge and understanding in the topic area?	4.6
Overall	4.4/5

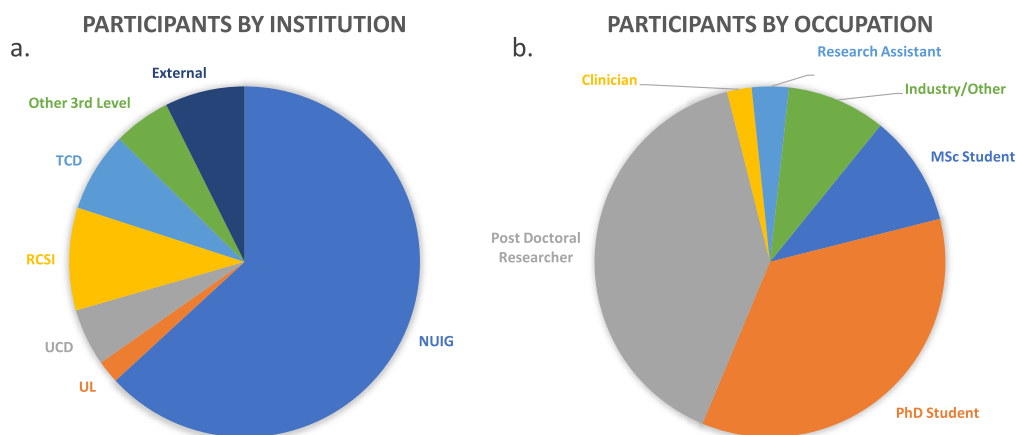


Figure 4. Fundamentals in Medical Device Design and Regulation e-Learning Course (2017 – 2020). Total course participant data (93 participants) as broken down by affiliated institution (a) and occupation (b). National University of Ireland Galway : NUIG; University of Limerick: UL; University College Dublin: UCD; Royal College of Surgeons Ireland: RCSI; Trinity College Dublin: TCD; External: Industry/Other.

Furthermore FMDDR, in support of structured PhD programmes, was European Credit Transfer and Accumulation System (ECTS) accredited for postgraduate students prior to its launch in December 2017 through the National University of Ireland Galway [24]. Some 27 of 93, or 29%, of course participants indicated their intention to use the course for ECTS purposes. FMDDR is also designed, by means of CRDI open badge accreditation, to support continuous professional development for the more advanced clinical, research academic or industry practitioner. Open badges are verifiable, portable digital badges with embedded metadata describing skills and achievements and are shareable across the web [25]. To date each of the 93 course participants has been issued with a certificate of completion and CRDI open badge.

Case study development

To underpin EURMD content delivery, and further its relevance to users, industry and notified body case study videos were created in collaboration with Aerogen and NSAI. The videos speak firstly to the device development journey and regulatory considerations required of the device developer from product ideation through to market launch, and secondly, to the requirements of medical device conformity assessment from the perspective of the notified body. The initial video case study content (regulatory material / scripts) was developed by CRDI and honed iteratively through a review and feedback process involving the NSAI and Aerogen with the aim of ‘bringing to life’ complex regulatory concepts from the perspective of the notified body and manufacturer in the first instance, and to reflect the distilled format of delivery of the course material in the second. Subsequently, on completion, the suite of case study videos was incorporated into the module on a topic by topic basis as appropriate.

Web portal development

To complement the e-Learning and to support active research programmes, we are developing a framework for a searchable online web portal (pre-launch test site: medtechtranslate.org).

The portal concept is based on a well-established model of medical device development (Stanford Stage Gate Process of Medical Device Development), a five-phase ‘go-no-go’ gated model which captures process complexity from product formulation through to post-market surveillance (Figure 5) [26]. Medtech Translate is being devised to impart fundamental regulatory concepts in a stage-of-development oriented manner, and as such its resources align closely to the medical device design and development process. In addition, the portal will also direct users to appropriate regulatory organisations, provide access to clinical support as well as pertinent resources and documentation.

Importantly, to enhance the impact of project resources much of the content, video case studies and interactive resources developed for the EURMD e-Learning were devised to populate and enhance delivery of regulatory information via the Medtech Translate portal. Significantly, this suite of regulatory training and information supports, used in combination or separately has, due to the online nature of its delivery, the potential to bring fundamental training to clinical research and innovation audiences outside of Ireland, to European audiences and beyond.

In order to strategically guide project advancement Medtech Translate’s framework and content development has been underpinned by an iterative three-stage stakeholder review process involving CRDI, CÚRAM and our project collaborators to include the National Standards Authority of Ireland, Ireland’s designated Notified Body; the Health Product’s Regulatory Authority, the National Competent Authority; a Quality and Regulatory Affairs expert from Aerogen Ltd. and representation from HRB CRDI on behalf of the

Medtech Translate Portal Design Framework 'Stage-gated' model of device design

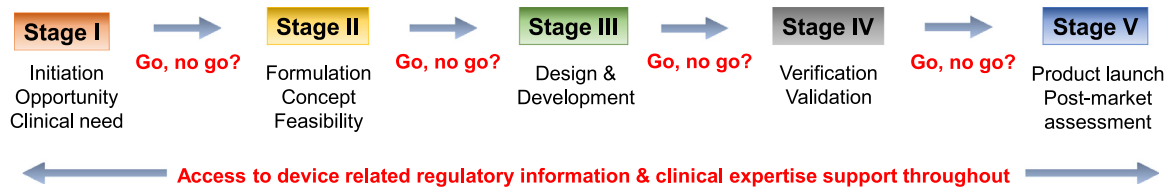


Figure 5. The medical device development journey as described by Medtech Translate builds upon a model describing the product realisation process as five discrete stages. Regulatory information, as delivered by Medtech Translate, is interspersed with a set of critical considerations, or 'go – no go' decision gates, at the end of each stage. These considerations relate to project feasibility and planning, and also advise on expected deliverables as well as key decisions relating to the medical device regulatory approvals process. Equally, Medtech Translate is structured to provide members with access to pertinent clinical advice or support at all stages of the development journey. Adapted from: Pietzsch JB, Shluzas LA, Paté-Cornell ME, Yock PG, Linehan JH. *J Medical Devices. Transactions of the ASME* 2009; 3(2): 021004.

national clinical research infrastructure. The review process comprised 3 meetings (initial, interim and final) at which progress and approach were evaluated. The web portal's functionality and regulatory content were appraised, gaps in message identified and potential areas for stakeholder contribution explored. Meeting outcomes were followed up, actioned, implemented and signed-off at subsequent review meetings or through one-on-one communications. The review process served to expedite the completion of the work whilst bringing together diverse yet strategically chosen perspectives central to Medtech Translate's primary purpose and ultimately to enhance the impact and message of the resource. In parallel with the e-Learning content the regulatory material used to populate the Medtech Translate portal underwent external expert review to ensure the validity and veracity of the content prior to launch.

On launch, Medtech Translate will, in addition to regulatory guidance and information, offer a clinical support function which provides users with access to relevant clinical device development expertise and specialist clinical trials support. This function, developed in collaboration with HRB CRCI (which coordinates the national clinical research network) is designed to identify the clinical expertise and experience required to support device design at any stage of development. Matching of suitable experts, identified through Medtech Translate and / or HRB CRCI databases, to device developers will be coordinated by the partnership and will be formulated to support existing HRB CRCI initiatives including their National Study Feasibility Programme [27].

Discussion

Our work to date, in recognition of the importance of incorporating regulatory concepts and the clinical perspective from the earliest stages of the device development journey, aims to address the recognised paucity of regulatory knowledge/training in our target audience whilst supporting access to clinical expertise in the device innovation space. The particular challenge in respect to this was how to optimise participation and meet the learning needs of diverse audiences. To this end we focused on harnessing a collaborative multifaceted (academic, regulatory and industry) approach to the origination of high-quality, sector focused, digital learning and information platforms. Moreover, in reaching out to academia and clinicians our work aligns closely with research and innovation priorities identified at EU level which seek to address regulatory impediments to, and to increase the impact of, Medtech innovation through the strengthening of regulatory sciences and supporting regulatory scientific advice in these cohorts [7,28].

Our method of e-Learning design and delivery serves to juxtapose core principles of device design and development with regu-

latory concepts central to the successful translation of medical device research for the clinic. This approach is important in that it addresses directly a need for the development of skills relevant to industry and academic entrepreneurship, whilst promoting an appreciation of: 1. the importance of incorporating regulatory principles and concepts from the earliest stages of device research and 2. the potential of regulation to impact upon device development and innovation processes.

The novelty of this work stems from the fact that, in addition to e-Learning, we are looking beyond a formal style of knowledge delivery. The information delivered as part of FMDDR was designed to align with, and will be delivered in formats complementary to, the regulatory information and clinical expertise being delivered through the Medtech Translate portal. Furthermore, this work is also unique in that output delivery is not commercially driven and has been specifically developed in support of medical device research and development in clinical academic and early innovation settings, nor is it, unlike a large number of regulatory training offerings available online at present, targeted at those seeking a formal professional regulatory qualification.

When discussing device design and development it is important to remember that it is not a unidirectional, one-task-at-a-time process. Indeed, many of its facets, to include the manufacturer's regulatory considerations are complex, frequently run in parallel, overlap and often benefit from an iterative approach. A cyclical or iterative approach from concept development through to commercialisation can benefit the manufacturer in that it serves to keep their development team focused on several critical project-related issues (to include regulatory compliance) at any given time.

In recognition of the multifaceted nature of device development the Medtech Translate model has been designed to be scalable with the portal having the inbuilt capacity to incorporate requirements relating to other device lifecycle considerations. To this end, work has begun on the development of e-Learning and portal content describing the device related quality management systems under EUDR and ISO standard requirements with capacity to expand this remit to other key aspects of the device lifecycle including health economic evaluation, re-imburement and clinical trial-relevant metrics. This approach is well-aligned with, and open to the integration of, the work of other CÚRAM-based translational research focused groups who are developing methods for device-focused clinical and economic evaluation as well as novel biostatistical design approaches for medical device clinical trials [29–31]. CÚRAM, as the SFI Research Centre for Medical Devices, provides an ideal methodological test ground for our resources as it represents a microcosm of innovative patient-focused clinical-academia-industry collaboration.

From a strategic perspective this work is also of value to our project partners in that it promotes entrepreneurship and serves to further their respective outreach and education objectives by enhancing regulatory awareness in the field; promoting quality in regulatory approval submissions; enhancing clinical academia-industry collaboration and supporting medical device clinical trials activity. The HPRA, for example, in its 2016 – 2020 strategic programme, identifies supporting life sciences and the leveraging of new technologies for patient benefit amongst its strategic objectives [32]. Equally the NSAI, is committed to 'actively engaging with key stakeholders to disseminate technical knowledge' and 'to targeting and promoting NSAI activities to research and innovation communities and third level institutions' [33]. Correspondingly, HRB CRCI, mandated in its role as national clinical research network coordinator to support trials feasibility, and through its association with the national enterprise agency, 'Enterprise Ireland', is strategically placed to facilitate access for clinical academics, small-medium enterprises and high potential start-ups to our e-Learning and Medtech Translate portal with a view to supporting device innovation processes and enhancing device investigation capacity in the sector.

However, despite the success of the work to date, some limitations and difficulties need to be acknowledged. In the first instance the cost of development of each resource is considerable and may be prohibitive for those considering a similar approach in other projects. Equally, the subsequent maintenance of these outputs in terms of personnel hours, expertise and technical support is not inconsequential. As a result we relied greatly, throughout the process, on 'in kind' access to much of the expertise and opinion required to make the ideation and development of this work viable.

Also, importantly, an ongoing concern throughout was that the material and information made available via the e-Learning, and through Medtech Translate in particular (as a public facing resource), could be considered by end users as being both definitive and prescriptive in terms of the legislation and/or construed as a checklist resource for achieving a CE mark and access to market. As such, every effort was made in the generation of these outputs to ensure that only primary sources were referred to in the text and that users are continually reminded that the platforms are solely designed for education and information purposes and should not be considered as a categorical interpretation of the Directives, the Regulations or indeed their supporting materials.

Moreover, having successfully integrated the e-Learning into academic streams we must now look to growing, in parallel with the initial strong uptake from clinical research and academia, our external innovation audience. It will be important for sustained growth in the sector to ensure that this cohort of device developers are aware of the regulatory requirements for market access and, as such, have easy open access to training and information tools in this regard. Correspondingly, we would envisage Medtech Translate acting for this cohort as a conduit to the clinical expertise necessary for basic research development and clinical trial support. We also anticipate that Medtech Translate will, through its linkages to the national clinical research and innovation support infrastructure, serve the increasing need for industry to be part of an integrated ecosystem comprising academia supported by national enterprise strategies [8].

In conclusion, the introduction of the EUDR has the potential to significantly impact clinical research and commercialisation activities EU wide. Effective navigation of regulatory processes is key to the delivery of new devices to patients and to the EU market. As such, training and access to pertinent legislative guidance and clinical expertise are vital to ensure sufficient levels of regulatory proficiency among health research audiences to support medical de-

vice research translation and continued buoyancy in the Medtech market.

Strong, positive sector relationships and clinical engagement are required to harness the appropriate expertise to meet knowledge gaps in the area. Our work benefits from an interdisciplinary approach to regulatory knowledge delivery and was borne of an identified need for a coordinated stakeholder response to Government and EU policy by supporting clinical – academic led growth in the sector. Our researcher training and support resources benefit from the involvement of clinical, academic, industry and regulatory stakeholders as well as the support of the national clinical research infrastructure. This joint approach to regulatory knowledge delivery and clinical engagement strategically positions the partnership to support the expansion of Ireland's, and Europe's, position as a global leader in healthcare technology innovation.

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Ethical approval

Not required.

Declaration of Competing Interest

None declared.

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