JOURNAL of MEDICAL DEVICE REGULATION

MAY 2023 SPECIAL REPRINT

Journal of Medical Device Regulation, 2023, 20(2), 45–56

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Publisher

Published by Global Regulatory Press
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Perceived training needs of regulators, Notified Bodies and clinicians for successful implementation of the EU MDR: survey results

Introduction/background

The increasing complexity of new medical devices fuels the discussion about the need for a 'regulatory science' for medical devices, to be developed in parallel to the implementation of Regulation (EU) 2017/745 on medical devices (MDR). The combination of new materials (e.g. in tissue engineering), new methods in testing (e.g. computer-aided modelling, simulation) and new technologies (e.g. neuroprosthetics, artificial intelligence) makes it all too obvious that regulators, Notified Bodies and clinicians (trialists) must keep pace with technological developments and continually develop their regulatory capabilities.

For over a decade 'regulatory science' has been discussed and concepts developed as instruments for improving professional skills and capacity of regulators and for advancing methodologies for regulation. In 2011, the US Food and Drug Administration (FDA) published its first strategic plan for regulatory science[1] followed by a detailed report on *Advancing Regulatory Science at FDA – Focus Areas of Regulatory Science (FARS)* in 2021[2]. In 2018, the European Medicines Agency (EMA) launched its strategy for *Regulatory Science to 2025*[3], followed by a detailed list of *Regulatory Science – Research Needs* in 2021[4]. However, most often the term is used in the context of medicines, and ideas for regulatory science for medical devices are still in their infancy, at least in the European Union (EU). In the USA, the FDA started to develop concepts in 2010, while the uptake of reflections on regulatory science started nearly a decade later in the EU in the context of the implementation of the new Regulation.

The scientific methods used in regulatory processes (as well as by other actors in the process of evidence generation, such as clinical research and health technology assessment (HTA)) encompass a wide range of methodological knowledge (from study designs for safety and efficacy assessment to quality and performance assessment in the post-marketing phase) of different scientific disciplines. So far, some post-graduate training institutions offer 'regulatory science' courses for professionals in the market access of pharmaceuticals, but advanced training is still rare and almost non-existent for the EU medical device sector. However, the demand for appropriately trained personnel in regulatory authorities, in Notified Bodies, for clinical trialists and in clinical expert panels is high.

Within this context of increasing awareness of needs to develop regulatory science further for medical devices, the Coordinating Research and Evidence for Medical Devices (CORE-MD) project,

running from April 2021 until March 2024, has been set up to accompany the implementation of the MDR in Europe. It reviews methodologies for the clinical evaluation of high-risk medical devices in order to translate expert evidence into advice for EU regulators and to recommend an appropriate balance between innovation, safety, and clinical effectiveness. Furthermore, CORE-MD provides recommendations on new trial designs that can contribute to regulation, and offers advice on methods for aggregating real-world data from medical device registries and experience from clinical practice. The CORE-MD consortium involves medical associations, EU regulators, national public health institutes, Notified Bodies, academic institutions, patient groups, and HTA agencies, with participation of manufacturers' trade associations.

A further task within CORE-MD is to develop a 'roadmap' for educational and training courses for successful implementation of the MDR. To prepare recommendations for the roadmap, a survey among regulators, Notified Bodies and clinicians was launched in summer 2022 to assess the perceived needs for advanced education and training in procedural and methodological knowledge. It is the intention of this article to report the results of the survey, which will be used as the basis for establishing a curriculum on regulatory science for medical devices, as well as recommendations for next steps.

Methods

An online survey was set up to ask about perceived needs for training in regulatory sciences, core methodological competencies, as well as the view on training formats and modalities. The survey was structured into different chapters such as demographics, occupation and education, training, core competencies and training needs, training formats and modalities, and additional comments/follow-up/results. The core competencies were derived from looking through offered trainings and curricula as well as exploratory consultations with stakeholders. A table with public health competencies was used as a possible example for this list[5] and the core competencies for the assessment of high-risk medical devices were structured according to the development cycle of medical devices[6]. In most cases, the survey contained single or multiple choice questions. For clinicians, additional questions were added about 'knowledge on regulatory affairs/sciences', which only showed up if the category 'clinician' was selected as 'main employment'. Also, other questions had different follow-up questions depending on the answer(s) given beforehand.

The analysis of the survey was performed in Microsoft Excel including all survey results except the pilot surveys. The answers from respondents from all countries were included. The rationale was to get an overall picture of professionals working in the field of regulatory sciences, considering that professionals could change jobs and countries (especially clinicians, who represent the majority of

survey respondents). In addition, the survey did not enquire about home country or place of education, it was specifically asking about the country of current main employment. However, a sensitivity analysis was done by leaving out the non-EU/European Economic Area (EEA) countries, but by including the United Kingdom (UK) whose legislation is still based on EU Directive 93/42/EEC and Turkey who transposed the MDR into their national legislation. Furthermore, all respondents that were part of an EU expert panel for the evaluation of medical devices or *in vitro* diagnostics (IVDs) were included. The sensitivity analysis was done with regard to the questions on the six domains of the core competencies including the relevant skills. In total, 409 people responded to the survey.

Results

Demographics, occupation and education, training of survey respondents

Only the most important and relevant information on basic characteristics of the survey respondents are presented in this article. Since the main stakeholders in the implementation of the MDR are Notified Bodies, regulators and clinicians, the survey respondents were asked to select which of these three categories defined best their main employment, so that the analysis could identify potential differences between these groups. Most survey respondents were clinicians (67.97%, 278 people) and around a seventh were regulators (14.18%, 58 people). The remainder of the respondents were Notified Bodies (9.05%, 37 people) or 'other' employment category (8.80%, 36 people). Some of the other employment options mentioned were in the fields of research/engineering (12 people), industry (five people), legal (five people), patient organisation (two people), and consultancy (two people).

For Notified Bodies, the top two EU/EEA countries where respondents worked were Germany (18.92%, seven people) and Poland (13.51%, five people). For regulators these were Germany (22.41%, 13 people) and Ireland (10.34%, six people); for clinicians Germany (13.67%, 38 people) and Croatia (10.07%, 28 people). For the 'other' employment category, Belgium (19.44%, seven people) and the Netherlands (16.67%, six people) were among the most selected EU/EEA countries. In total, 72 of 409 respondents (17.60%) indicated 'other country', most of them clinicians (57 people), nine Notified Bodies, one regulator and five people from the 'other' employment category. Ten people (four clinicians and six Notified Bodies) indicated that their country of current place of work is Turkey and 17 people (two Notified Bodies, 14 clinicians, one 'other') indicated the UK. From those who selected 'other country', six were part of an EU expert panel for the evaluation of medical devices or IVDs.

One Notified Body (2.70% of Notified Bodies) and one regulator (1.72% of regulators) participated each in one expert panel. Of the 64 clinicians that were part of an EU expert panel (23.02% of clinicians), seven were part of two EU expert panels. Eighteen clinicians participated in the screening

panel (determines whether there is a need for a scientific opinion), 12 in the circulatory system panel, nine in the general and plastic surgery and dentistry panel, and eight in the neurology panel. No one from the survey respondents was part of an EU expert panel on endocrinology and diabetes.

At least 50% or more of each employment category indicated that they were at senior or executive level. The highest number of respondents at entry level was seen for regulators (17.24%, 10 people). For Notified Bodies, most mentioned specialties were engineering (43.24%, 16 people) and human medicine (32.43%, 12 people). For regulators, it was similar, 34.48% (20 people) indicated engineering and 17.24% (10 people) human medicine. Not surprisingly, 94.24% of clinicians (262 people) stated human medicine as their specialty. The 'other' employment category showed the following: 22.22% (eight people) indicated engineering and nearly a fifth (19.44%, seven people) stated 'other specialty'. Of all respondents that selected human medicine (289 people), nearly half indicated circulatory system (44.64%, 129 people) as their main specialty, followed by neurology (13.84%, 40 people) and 'other specialties' (11.07%, 32 people).

More than half of Notified Bodies (67.57%, 25 people) and of the 'other' employment category (63.89%, 23 people) ever attended medical device regulatory sciences education or training. However, more than half of regulators (53.45%, 31 people) and clinicians (65.47%, 182 people) did not.

Clinician respondents´ knowledge about regulatory affairs/sciences

Survey respondents who selected clinician as their main employment received additional questions in order to identify their knowledge level about regulatory affairs/sciences in general. Nearly two-thirds of the clinician respondents (65.47%, 182 people) indicated that they have a general idea or a very good understanding of the legislation and the regulatory system. Around a third (33.81%, 94 people) declared that they did not know how the legislation, evaluation, approval and surveillance process works. 0.72% (two people) indicated 'other'. The other questions were directed towards their knowledge on the responsibilities and processes within the medical device regulatory system:

- More than half of the clinician respondents (56.84%, 158 people) correctly stated that the manufacturer is responsible for demonstrating the clinical effectiveness. The remainder allocated this responsibility to the national regulatory agency (31.65%, 88 people), Notified Bodies (7.91%, 22 people), academic trialists (2.88%, eight people) or other (0.72%, two people).
- Nearly half of the clinician respondents used the EMA website (47.12%, 131 people) and published medical literature (44.96%, 125 people) as sources for information to verify the safety of a medical device. 39.57% (110 people) would ask the manufacturer, 30.94% (86 people) would look at reports from medical device registries, 18.71% (52 people) would search the European

Commission website and 13.31% (37 people) would conduct a Google search. 1.80% of the clinician respondents (five people) mentioned other sources such as the European Database on Medical Devices (EUDAMED), the Manufacturer and User Facility Device Experience (MAUDE) database, the Ministry of Health and the national regulator. Multiple options could be selected.

- Only 1.44% of the clinician respondents (four people) would not report a concern around the safety of a device. The remainder of the clinician respondents would report it and the most selected body for sending the report to is the national authority with 39.57% of the clinician respondents (110 people), followed by contacting the manufacturer (23.38%, 65 people), contacting hospital administration (19.06%, 53 people) and contacting a Notified Body (16.19%, 45 people). 0.36% (one person) indicated 'other'.
- More than half of the clinician respondents (57.91%, 161 people) stated that training on regulatory affairs/sciences could help them to verify the safety of the devices better. Half of the clinician respondents (51.08%, 142 people) also stated that it would allow them to participate in an evaluation process of a medical device. A third (32.73%, 91 people) also indicated that it would help them in understanding the value of registries in post-market surveillance. 12.95% of clinician respondents (36 people) stated that they do not think it will make a difference in their work, however, one of them also selected the option 'Better verification whether the devices that I use are safe'. Only 1.08% of clinician respondents (three people) answered that regulatory affairs/sciences is not easy to understand for a person educated as a medical doctor, that healthcare professionals are not trained in medical devices compared to medicines, and that it would help to interpret the regulations better.

Identified needs for methodological expertise and educational requirements

The core competencies (*see* Table 1) were structured into six domains. Three of these domains listed respective detailed skills (i.e. clinical investigation, legal/regulatory for market access, and post-market surveillance).

Table 1. Core competencies for the assessment of high-risk medical devices

Domains	Skills (throughout the lifecycle of a medical device)
1. Pre-clinical testing (methodology and evaluation) (e.g. design and development of medical devices)	
2. Drafting a scientific advice to manufacturers	

Domains	Skills (throughout the lifecycle of a medical device)
3. Clinical investigation (methodology and evaluation)	Study designs and their advantages/disadvantages
	Concepts of unmet need in patient populations
	Methods and time points for patient involvement/engagement
	Choice of comparators (standard of care versus sham versus placebo)
	Outcomes' measurements and instruments (standardised and validated instruments)
	Assessment of benefit-risk ratio and thresholds for acceptability
	Use of data from equivalence (biocompatibility standard)
	(Functional) safety and performance assessment
	Methods for the evaluation of specific high-risk medical devices (e.g. artificial intelligence, combination devices, devices derived from tissues and cells of human origin)
	Systematic literature review (guidance for method and process)
	Medical statistics (e.g. power calculation of trials, p-values)
	Clinical epidemiology (data and sources for burden of disease, prevalence, incidence)
	Data analysis (different for processing primary data)
	Ethics in clinical trials (e.g. recruitment, patient consent, information on uncertainties)
4. Legal, regulatory for market access	Regulation (EU) 2017/745 on medical devices: requirements, procedures, implementation, update on regulatory developments
	Classification of devices, especially borderline devices
	Quality Management System – ISO 13485
	Good Clinical Practice – ISO 14155
	Good Manufacturing Practice – ISO 13485
	Risk management – ISO 14971
5. Post-market surveillance	Registers and post-launch evidence generation (types of registers, data collections)
	Drafting a post-launch plan
	Collection of vigilance data
	Post-market clinical follow-up plans and evaluation reports
	Types of post-market surveillance data
6. Soft skills (e.g. medical writing, project management)	

Survey respondents could select one of five options for every domain and skill:

1. 'Does not apply (not relevant for my job)'
2. 'I have no knowledge of this domain'
3. 'I have awareness level knowledge or skills'
4. 'I have practical knowledge or skills'
5. 'I have advanced knowledge or skills'

If option 1 was chosen, the respective skills of the domain were not shown. However, if someone selected option 2, the respective skills were shown since the aim was to offer the respondents a chance to differentiate their knowledge further into specific skills. In some cases, the respondents took the opportunity to provide distinct answers for the skills; in other cases, the answer option 2 (I have no knowledge of this domain) was repeated for the skills. To calculate percentages for the *skills*, the total number who selected option 2, 3, 4 or 5 in the respective domain question was used as the denominator.

The main results are presented below; the focus was on highlighting those domains/skills where the stakeholder groups were lacking knowledge:

1. **Pre-clinical testing (methodology and evaluation)** – design and development of medical devices: In general, the group of Notified Body respondents showed the largest proportion of people with practical knowledge (35.14%, 13 people) and advanced knowledge (24.32%, nine people). Clinician respondents had the highest proportion of people with no knowledge (25.54%, 71 people) or for whom it was not applicable (21.94%, 61 people). Also 22.41% (13 people) of regulator respondents did not have knowledge of this domain.
2. **Drafting a scientific advice to manufacturers**: In general, Notified Body respondents and 'other' employment category respondents had practical (27.03%, 10 people; 27.78%, 10 people) and advanced (8.11%, three people; 8.33%, three people) knowledge or skills. Clinician respondents had the highest proportion of people with no knowledge (34.17%, 95 people), followed by regulator respondents (25.86%, 15 people).
3. **Clinical investigation (methodology and evaluation)**: The majority of all groups had awareness level or practical knowledge. Some regulator respondents had no knowledge of this domain (20.69%, 12 people). In total, this domain was applicable for 91.44% of survey respondents (374 people), who subsequently received the questions on relevant skills. Specifically, 21–30% of Notified Body respondents had no knowledge in two skills: 'Methods and time points for patient

involvement/engagement' and 'Clinical epidemiology'. Furthermore, 31–40% of regulator respondents indicated for five skills that they had no knowledge ('Concepts of unmet need in patient populations', 'Methods and time points for patient involvement/engagement', 'Choice of comparators', 'Methods for the evaluation of specific high-risk medical devices', and 'Data analysis'). For the skill 'Clinical epidemiology' over 41% stated that they had no knowledge. Also 21–30% of regulator respondents indicated seven different skills where they were lacking knowledge ('Study designs and their advantages/disadvantages', 'Outcomes' measurements and instruments', 'Assessment of benefit-risk ratio and thresholds for acceptability', 'Use of data from equivalence', 'Systematic literature review', 'Medical statistics', and 'Ethics in clinical trials'). From clinician respondents, 21–30% stated that they had no knowledge in '(Functional) safety and performance assessment' and 31–40% indicated this for 'Use of data from equivalence' and 'Methods for the evaluation of specific high-risk medical devices'. From the survey participants of the 'other' employment category, 21–30% said that they had no knowledge in 'Concepts of unmet need in patient populations', 'Methods and time points for patient involvement/engagement', 'Methods for the evaluation of specific high-risk medical devices', 'Clinical epidemiology' and 'Data analysis'. Overall, 35.03% (131 people) of all survey participants for whom this domain was applicable stated that they had no knowledge in 'Methods for the evaluation of specific high-risk medical devices'.

4. **Legal, regulatory for market access**: Clinician respondents were lacking knowledge about legal and regulatory issues (36.69%, 102 people). In total, this domain was applicable for 86.31% of survey respondents (353 people), who subsequently received the questions on relevant skills. A total of 21–30% of regulator and of clinician respondents respectively had no knowledge of 'Good Clinical Practice'. From clinician respondents, 31–40% were lacking knowledge about 'Regulation (EU) 2017/745 on medical devices' and about 'Classification of devices'. Furthermore, over 41% of clinician respondents did not have skills in 'Good Manufacturing Practice', 'risk management' and 'Quality Management System'.
5. **Post-market surveillance**: Notified Body and regulator respondents had practical knowledge (43.24%, 16 people; 34.48%, 20 people) and advanced knowledge (37.84%, 14 people; 22.41%, 13 people). Clinician respondents were lacking knowledge about 'post-market surveillance' (23.74%, 66 people), followed by regulator respondents (8.62%, five people). In total, this domain was applicable for 89.00% of survey respondents (364 people), who subsequently received the questions on relevant skills. Over 41% of clinician respondents did not have any knowledge in 'Drafting a post-launch plan', 'Collection of vigilance data' or 'Types of post-market surveillance data'. Also 31–40% of clinician respondents were lacking knowledge in 'Registers and post-launch

evidence generation' and in 'Post-market clinical follow-up plans and evaluation reports'. Furthermore 31–40% of regulator respondents had no knowledge in 'Drafting a post-launch plan' and 21–30% did not have knowledge in 'Collection of vigilance data', 'Post-market clinical follow-up plans and evaluation reports' or 'Types of post-market surveillance data'.

6. **Soft skills (e.g. medical writing, project management)**: Some regulator respondents were lacking soft skills (20.69%, 12 people). The majority of all survey respondents (53.55%, 219 people) had practical or advanced skills.

Within the sensitivity analysis, the results of the core competencies were re-analysed. For some answer possibilities no change was seen, for some a minor change was identified; however, the overall meaning of the results did not change to a notable extent.

Survey participants could select the top three skills in which they would like to have training over the next three to five years. All stakeholder groups mentioned 'Assessment of benefit-risk ratio and thresholds for acceptability' among their first, second and/or third choice for training opportunities. 'Pre-clinical testing (methodology and evaluation): Design and development of medical devices' was also frequently stated as a first choice by Notified Bodies and regulators. For clinicians, 'Study designs and their advantages/disadvantages' was the most frequently mentioned skill as a first choice. For the 'other' employment category, 'Regulation (EU) 2017/745 on medical devices: requirements, procedures, implementation, update on regulatory developments' was the skill that was indicated the most as a first choice.

Training, training formats and modalities

Survey respondents could select one or more groups (Notified Bodies, regulators, clinicians) for which they perceived training needs. Every group selected their own group as having the highest need for training. In total, 72.37% of survey respondents (296 people) indicated that the highest need for training was for clinicians, which was followed by 48.17% (197 people) for regulators and 41.32% (169 people) for Notified Bodies. 12.71% of all survey respondents (52 people) indicated that they do not know or do not have any opinion on this. Only 0.98% of all respondents (four people) indicated that there is no training needed for any of the three groups.

The follow-up question on the preferred format of the training allowed multiple selections (as a denominator, the maximum number of respondents from every employment category that that said 'yes' for any group was used, which was 320 people). In total, the offered options were selected in a similar frequency, which ranged from 44.38% of survey respondents (142 people) for practical training on the job (advanced internships in organisations and mentoring programmes), to 45.00%

(144 people) for block training modules (several days in a row), to 47.19% (151 people) for lifelong upskilling and reskilling/continuous training, up to 49.69% (159 people) for training in single days.

All survey respondents received the question on the preference regarding the composition of the training group. Only one option could be selected. Around a third of every group (Notified Body, regulator, clinician, 'other' employment category) that participated in the survey preferred training dedicated to the specific target group. In total, 15% of all survey respondents (63 people) favoured training across the target groups. A high percentage of survey respondents, in particular 40% of clinician respondents, did not have an opinion on this. The smallest percentage of every group stated that it depended on the topic/module (in the case of Notified Bodies it was equal with training across target groups).

Discussion

In a recent position paper from the Medical Device Coordination Group (MDCG), capacity building for the transition to the MDR and Regulation (EU) 2017/746 on *in vitro* diagnostics (IVDR) is recognised and emphasised[7]. Capacity building comprises not only good knowledge on the legislation (MDR, IVDR), regulatory policies and instruments as well as MDCG guidance documents, covered under the umbrella term of 'regulatory affairs', but also more in-depth and specific knowledge on advanced methodologies for the evaluation of medical devices in pre-clinical and clinical investigations and post-market surveillance evaluations. The development of new methodologies for better regulation is often referred to as 'regulatory science', defined as 'the science of developing and validating new standards and tools to evaluate and assess the benefit/risk of … [medical devices and IVDs] facilitating sound and transparent regulatory decision making'[8]. Increasing the efficiency of the regulatory system and improving its effectiveness on the basis of scientific research results is of great importance for the successful implementation of the MDR and IVDR. To support this endeavour, it is the intention of CORE-MD to develop recommendations for advanced education and training courses.

A review of published literature on skills in regulatory science, a landscape overview of existing advanced educational programmes, and exploratory consultations with stakeholders complemented the survey as the basis for a comprehensive list of domains and skills. These domains and skills throughout the lifecycle of a medical device might form the starting point for specific curricula. In summary, the CORE-MD survey results indicate that regulators, Notified Bodies and clinicians need training in pre-clinical testing (methodology and evaluation), drafting scientific advice to manufacturers and post-market surveillance. Especially clinicians, who contribute to the regulation of medical devices in their role as trialists and/or members of an expert panel, have to ensure that the devices in use in clinical practice are safe. They are lacking knowledge regarding legal and regulatory

processes and guidelines for market access. Since regulators, Notified Bodies and clinicians require different skills relating to clinical investigation (methodology and evaluation) and different depth and breadth of knowledge, it is advisable to offer modular training and educational courses that are fit for the different requirements. Any offers for training and education must be for the specific stakeholder groups and their tasks in the regulatory process to be capable of fulfilling their roles and assignments professionally.

The results must be interpreted in the context of several limitations. Since this survey was self-administered and voluntary, a selection bias might be present, as only those interested in the topic participated in the survey. Those respondents who are more confident with the assessment of high-risk medical devices and/or who have knowledge about the MDR (e.g. clinicians who contribute to expert panels might have distorted the answers positively), might be more likely to complete the survey than those with less knowledge/skills. Furthermore, respondents could have presented their answers more positively than they actually are and results might not truly reflect the educational status of the respondents. Additionally, the conclusions are limited by the range of individuals responding in each type of organisation (regulators, Notified Bodies and clinicians). In particular, as the group of clinicians responding to the survey were heterogeneous, a generalisation should be done with caution. It needs to be considered that the knowledge gaps mentioned are based on previous education and experience, and generalisation to the stakeholder group in general might be limited.

Nevertheless, nearly all survey respondents stated that they perceive a need for training courses in medical device regulatory science for the three stakeholder groups. The highest need for training was indicated for clinicians (72%), which was followed by regulators (48%) and Notified Bodies (41%).

Conclusion/summary

To summarise, the survey showed ‘real’ gaps (defined by critical skill needed by a stakeholder to do their job correctly), and ‘ideal’ gaps (defined by additional nice-to-have skills). The ‘real’ gaps identified are as follows for each stakeholder group:

- For clinicians, who want to contribute to the approval of safe and effective medical devices, the basics of European regulation, as well as training courses on clinical and post-market surveillance trial methodologies for participation in clinical investigations (as clinical trialists) and in conformity assessment (as medical experts). Internships with Notified Bodies and regulators (Competent Authorities) would complement with ‘on the job’ training.

- For regulators, horizon scanning for the advancement of methodologies for clinical investigations of new and emerging and hybrid technologies.
- For Notified Bodies, regular training courses on new MDCG guidance documents and on advanced methodologies to assess clinical data, especially in highly specific medical areas (e.g. artificial intelligence, robotics).

Finally – based on the perceived needs for training and educational courses in regulatory science – the CORE-MD consortium has called for action aimed at capacity building in favour of increasing the efficiency of the regulatory system for safe and effective medical devices and improving its effectiveness. Recommendations for the implementation of advanced training offers will be developed by the end of the CORE-MD project (March 2024).

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Acknowledgments: The authors thank their colleagues from Team-NB, BioMed Alliance and ESC who contributed to the development of the survey.

Funding: This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under grant agreement No 965246.