



Pitch LCRDM:

Medical Device Regulation and RDM support

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1. Goal (problem definition, solution direction) and demarcation of the subject.

The new Medical Device Regulation (MDR) will go into effect on May 26, 2021. This can apply to both nWMO and WMO studies/research with a medical device (including apps and software). When a medical device is used within a research context, it is not yet clear what possible research data management (RDM) tasks are required, what assistance can be offered and what should be stated in a data management plan (DMP).

The purpose of this task group is to:

1. to get an overview whether and, if so, how Universities and UMCs are preparing for the new MDR legislation
2. what support general RDM support (for example the central data steward) should be able to offer
3. what other support is offered within the (own) organization (regarding technological and associated monitoring or legal requirements)

2. Why is this of cross-institutional importance?

Although not all research organizations will have to deal with this new legislation, it appears that among RDM support employees, especially within the medical research field, there is a need to clarify the consequences of this new legislation. RDM support, such as data stewards, would like to be able to provide researchers with proper advice. Referral to the correct support desk can also be a suited option.

3. Deliverable/output, what will you deliver? (the “product”) and rough outline.

Output: document describing:

- a) Guidelines to determine for yourself when an app, tool or software is a medical device (evaluation of existing tools/decision trees).
- b) Which RDM support can generally be provided for research which includes medical device as defined in the Medical Device Regulation (MDR). This concerns both medical devices that are already on the market with/without CE marking, as well as new devices that are still under development/further developed during the study/project.

- c) Provide clarity regarding the scope of general RDM support responsibilities.
The researcher/PI is responsible. Which tasks fall under support by Privacy /ICT/Legal departments, which tasks fall under RDM support. What tasks fall under monitoring by a (clinical) monitor / 'Trial Bureau'.
Possibly while making use of example projects / showcases.
- d) d. What other support departments within a research organization should / could be involved?
Who / what is needed besides general RDM support to correctly refer to regarding MDR questions, both within as well as outside of your own research organization.

4. Demarcation: What is the task group not going to do?

The Task Group will not build an app/tool with a decision tree to determine when an app, tool or software complies with the MDR (it will evaluate existing ones).

This legislation relates in particular to research of a medical nature including eHealth solutions in UMCs, Universities and HBOs. Other research directions are excluded from this pitch for now.

5. Estimated project lead time and desired schedule

Lead time 2 to 3 months, 5-6x consultation:

Time required: on average 2h / wk

Start in the 2nd half of January 2021

Schedule:

1. Kick-off: introduction and division of tasks

What do we do. Who does what? How are we going to communicate / collaborate /...

2-3-4. meetings with feedback on findings and determine how to proceed

5. Concept deliverable

6. Final final report + final evaluation + closing Task group

6. What expertise / competences is / are required to form this task group?

6 to 8 active people, researchers and research support employees within RDM / MDR / IT / METC / Monitoring from academic hospitals and regional hospitals, universities and HBOs (universities of applied sciences), especially social sciences, public health, movement sciences.

Additionally, non-Task Group members can be involved in a consultative group.

7. And what resources do you think you need?

Help with manufacturing end product + publication thereof (document / translator / publication / communication /....)

8. What has already been known / done and why is that information insufficient?

Tools and information are already available on the website of the CCMO, but knowledge and demarcation regarding RDM are not mentioned and are often unknown.