MedTech Europe Guidance on Collaborative Research

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Introduction

To drive innovation in medical technologies and improve patient care, there is an increasing demand from both medical technology companies and Healthcare Organisations (HCOs), as well as other stakeholders involved in patient care, to collaborate on research projects. These collaborations allow parties to leverage each other's expertise and infrastructure to improve health care. There is a need for clear guidance on how to engage in these partnerships in a compliant and effective manner, ensuring that they do not constitute an inducement to HCPs or other relevant decision makers to prescribe, supply, recommend, buy or sell a medical technology.

This document provides such guidance, focusing specifically on the interactions between Member Companies and Healthcare Professionals (HCPs) and HCOs. Notably, the Guidance does not distinguish between Clinical and Non-Clinical Research; therefore, when referring to collaborative research, both types are included.

Examples

- The research opportunity involves a Member Company and at least one external entity (e.g., healthcare organisations, consortium, foundation, or society):
  - Collaborations with healthcare organisations.
- There is a shared and/or mutual benefit between the parties involved from undertaking the research together beyond general research benefits:
  - Both Member Company and Collaborating party (or parties) independently use resulting data to further their research missions, which should be advancing scientific knowledge, developing new product, improving patient care or contributing to broad healthcare field.
- Both Member Company and Collaborating Partner(s) actively contribute significant skills, experience and/or resource complementary to the collaboration (e.g. study objectives and design, methodology, protocol development, study conduct, statistical analysis plan, clinical study report and publication):
  - Member Company and the Collaborating party (or parties) discuss a general research idea and actively develop a clinical research project together or program where all entities provide input.

Questions & Answers

1. What is the general guidance on selection criteria of Collaborating parties and what key considerations should Member Companies take before engaging in Collaborative research activities?

- Collaborating parties should be selected on the basis of objective professional criteria and not in view of any past or future sales activities.
- Companies' policies should include:
  - disclosure requirements with respect to previous interactions;
  - measures to ensure compliance with laws & regulations.
- It is essential that Companies consider key factors, such as:
  - the review and approval/authorisation process;
  - due diligence criteria (i.e. third-party Due Diligence review);
  - budgeting and contracting processes;
  - permissible interactions during the execution of the research
  - other relevant considerations (e.g. conflicts of interest).
- It is advisable to have in place a review and approval processes (e.g. a review by an internal cross functional board) in order to ensure the proposed project is in alignment with internal procedure & definition and strategic evidence priorities, to identify business risks and to recommend mitigations for those risks. The Review Board may consist of cross functional reviewers including Clinical/Medical Science leaders, Legal & Compliance, Regulatory affairs, Data privacy experts, etc.
- In order to determine the party responsible for ensuring compliance with regulatory requirements, it is advisable to consult the applicable legislation and regulatory frameworks of the relevant jurisdictions.

2. What criteria should be considered for determining the legitimacy and purpose of Collaborative Research in the development and approval of medical technologies, therapies, or related services?

Apart from standard criteria that must be fulfilled for any type of research project (e.g., scientific and/or clinical merit, compliance with applicable laws and regulations), Collaborative Research is considered legitimate where the research project provides for a balanced research partnership with genuine scientific collaboration reflected through:

- continuous active intellectual contributions from all parties (not merely financial support)
- complementary expertise that enhances the quality of the research
- defined roles and responsibilities for all parties
- shared input into the design and implementation of the research project
- balanced decision-making process documented in agreements and
- equitable distribution of contribution and benefits.

3. What level of independence should companies ensure between decisions about collaborations and commercial decisions?

- To ensure a clear split between research and commercial decisions, decisions on collaborative research projects are not allowed to be taken or influenced by commercial focused employees.

- The general MedTech Europe rules regarding Research set out in Chapter 6 of the Code and the general principles of the Code shall be respected also in relation to transparency aspects and separation.

4. What measures should be in place to ensure that Collaborative research activities performed by Member Companies are in accordance with national laws and regulations, professional codes of conduct, ethical requirements, and applicable good practice guidelines?

- **Data Protection and Privacy:** defining roles and responsibilities in a contract in relation to compliance with GDPR.
- **Ethics and Informed Consent:** Ensuring all required ethical and regulatory approvals are obtained before research begins. Informed consent must be clear, voluntary, and GDPR-compliant. Maintain high ethical standards with ongoing oversight, in line with any applicable regulations.
- **Intellectual Property Rights:** Identifying, protecting, and properly managing IP rights among multiple collaborators can be challenging and requires clear agreements and a robust framework for intellectual property management.
- **Regulatory Compliance:** Depending on the nature of the study, compliance with regulations such as Good Clinical Practice (GCP), Good Laboratory Practice (GLP), or Good Manufacturing Practice (GMP) may be necessary to ensure the validity and reliability of the research outcomes.
- **Contractual Agreements:** Establishing clear contractual agreements between the collaborating parties is important to outline responsibilities, obligations, data sharing arrangements, intellectual property ownership and licensing, and dispute resolution mechanisms. Ensuring these agreements align with applicable European regulations is essential for compliance. It must outline the financial arrangements. The expected benefits for patients, the population or user groups should always be stated first, and outcomes should be measured. Travel costs shall be duly considered and documented in the management of Collaborative Research projects.
- **Cross-border Collaboration:** Coordinating and understanding country-specific regulations necessary to ensure compliance across borders.
- **Reporting and Disclosure Requirements:** This can include submitting study results, adverse events, or regulatory filings to appropriate authorities and stakeholders in a timely and compliant manner.

5. Can a Member Company sign a non-disclosure agreement (NDA) before entering in discussions with the Collaborating party?

Yes. The agreement could also cover the scenario that negotiations to enter a Collaborative Research project are not successful.

6. Which aspects need to be covered in a Collaborative Research agreement?

Member Companies need to ensure that written agreements clearly define roles and responsibilities, including study initiation, sponsorship, intellectual property ownership, financial support, transparency of involvement, reporting, data rights, publication registration, adverse event reporting, and dispute resolution[1].

[1] Code of Ethical Business Practice, Chapter 6: Research, p.50.

7. Can Investigator-initiated study (IIS) be reclassified or restructured into a Collaborative research agreement? If so, what are the key criteria for that transition?

Yes, an IIS may be reclassified or restructured into a Collaborative Research (CR) agreement, subject to the following conditions:

- the project's progression and development meet the necessary criteria;
- the project complies with the overarching principles of MedTech Europe Code of Ethical Business Practice
- the project satisfies the criteria for collaborative research (including but not limited to the identification of qualified partners, a clearly defined scope, the integration of resources and expertise etc.);
- it is documented in a specifically negotiated agreement tailored for the purpose of the collaborative research rather than through the restructuring or amendment of an existing agreement;
- the project does not constitute an inducement to healthcare professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell Member Company product(s).

The transition is only permissible from an IIS to a CR, and not vice versa. This restriction exists because collaborative research requires active contribution of skills, experience, and resources by the Member Company, which is not the case in an IIS where the third party independently manages all aspects of the research from the outset.

8. What happens if there are significant changes to the study concept, protocol or budget after approval and contract execution?

- Re-assessment of the project to determine whether it still qualifies as a Collaborative Research, potential new formal review and approval procedure by the Member Company internal board, depending on the significance of the changes and amendment of the Collaborative Research agreement accordingly.
- How to handle changes should be agreed in the contract, could e.g. be that an amendment is needed for major changes

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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