Hamilton Medical clinical investigation support. Guidelines

Requirements for clinical investigation support

Hamilton Medical is willing to support clinical investigations involving company products, provided they are aligned with the current interests of Hamilton Medical. An applicant must have the scientific, technical, and operational capabilities needed to conduct clinical investigations in accordance with local legislation and regulations as described in **ISO 14155 Clinical investigation of medical devices for human subjects — Good clinical practice.**

How to apply for clinical investigation support

You are invited to submit your proposal using the online request form. Please note that you must complete the form even if you have already spoken to a member of our Research and New Technology team about support for your research. Applications will be screened internally for completeness and reviewed by the Hamilton Medical Research team. This review will be based on, but not limited to, the following points:

- Scientific question, hypothesis, or claim
- Feasibility of the proposed investigation
- Proposed methodology
- Clear evidence that the investigation will being conducted according to ethical and medical standards as described in Good Clinical Practice (GCP) guidelines (e.g., GCP certification)
- Type of support requested
- Investigator's qualifications and expertise
- Alignment with Hamilton Medical's strategic planning for the relevant products/features/devices
- Availability of resources at Hamilton Medical
- Alignment of the funding request with fair market value
- Potential ethical issues

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Applicants will be notified about the outcome once a decision has been reached. Assuming the request is approved, the following documents must then be submitted and approved before support can be initiated:

- A fully executed agreement between the parties containing, if applicable: a) an equipment loan agreement, b) a data exchange agreement, and c) a financial agreement
- An EC/IRB and/or approval from the relevant health authorities

Processing of your personal data

By submitting a request for support, you confirm that you have read and agree to the terms of our privacy policy and warrant that you have the permission to share personal data. Personal data collected during the submission process will be used solely for the purposes of evaluating the applicant's proposal for a clinical investigation. If support is granted, this personal data may also be used for contracting purposes. Once the retention period has ended, your personal data will be deleted from our systems.

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