The Dexcom External Research Program

Program Description

- The Dexcom External Research Program encourages investigators, organizations, and industry to utilize CGM technology as part of their study programs and to pursue original diabetes-related research.
- Typical categories of research that may be eligible for support include:
    - Investigator-initiated studies (IIS)
    - Industry-sponsored studies using CGM as a diagnostic or data collection tool (e.g. pharmaceutical research)
    - Studies sponsored by non-profit groups or other research consortiums (e.g. Artificial Pancreas groups)
- Eligible external research is designed, implemented, and sponsored by independent clinical investigators, organizations, or industry sponsors. Dexcom does not design, conduct, or supervise the study, but may provide limited scientific, technical, data analysis or training assistance related to Dexcom technology.
- Any investigators, organizations, or industry groups requesting research support from Dexcom will serve as the sponsor of the proposed study. They will be expected to perform the responsibilities of 'sponsor' as defined by the United States Code of Federal Regulations (21 CFR, Subpart D) and ICH Guidelines for Good Clinical Practices (GCP) concerning Sponsor Responsibilities, as applicable. Sponsor responsibilities include, but are not limited to:
    - Designing the protocol and conducting the scientific investigation
    - Understanding and complying with any local regulatory requirements
    - Device Accountability (for studies using investigational product)
    - Monitoring the study
    - Reporting safety data to regulatory authorities, the IRB/EC, and Dexcom, as applicable
    - Registering the study on a public web site or any other venue required by law (e.g. www.clinicaltrials.gov)
- Dexcom will not formally commit to support any project without thorough scientific review of study-related materials and without verification that the research has been approved by proper governing bodies (e.g. IRB, EC, and FDA, as applicable). Upon review of study materials, Dexcom may provide comments or revisions to the proposed materials to be considered.
- Dexcom may support eligible studies by providing Dexcom products at agreed-upon rates, depending on the scope of the project.

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Submission and Review Process

Electronic submissions should be submitted through Dexcom's External Research web portal. Users must first set up an account from which they will be able to submit and track all projects.

Web Portal: http://www.dexcom-exrp.com/

The average total length of time from submission to communication of decision support ranges from two to six months, depending on a number of factors. Additional review time may be required as needed.

1. A complete online submission must be received in order for a research request to be considered by Dexcom for review. This submission includes basic information about the study sponsor, study objectives, expected timelines, product requested, and other relevant details.
2. Dexcom will acknowledge receipt of all research submission requests via e-mail; users can also track their project status under their web portal account.
3. A Dexcom committee with clinical, medical, regulatory, and technical expertise will review each submission. Decisions for support are made based on scientific merit as well as available resources and current company/research priorities. Groups should allow at least 3-4 weeks for initial committee review after a submission is received by Dexcom.
4. A formal notification concerning the status of each application (approved or declined) will be provided once the research proposal has been reviewed.

Approved Submissions

Upon approval of a research submission, Dexcom requires the following before initiating formal study support:

- Clinical Trial Supply Agreement, Purchase Order, or equivalent agreement, based on the scope of the project
- Verification of IRB/Ethics Committee Approval or equivalent, as applicable
- Final study protocol or synopsis – independent investigators and organizations only
- Notification of any local import requirements for international site locations, as applicable

Study Management

Dexcom requires the sponsor to provide the following for project maintenance:

- Timely product forecasts/requests
- Periodic study status updates (including protocol amendments, enrollment progress, study timeline changes, planned publications etc.)
- Reports of any adverse events or device malfunctions related to Dexcom products