Abbott
Diabetes Care

Investigator-Initiated Studies

Abbott Diabetes Care (ADC) strives to advance clinical and scientific understanding of the role of glucose levels on managing and improving people's health and well-being.

The Scientific Research Review Committee at ADC welcomes proposals from academic and community-based researchers worldwide who are interested in conducting their own research. Evaluation of proposals includes alignment with ADC's scientific research areas of interest, which are:

- Sensor-based glucose monitoring in the presence of comorbid conditions, for example kidney and cardiac disease
- Sensor-based glucose monitoring in T2 diabetes to optimize therapy
- Sensor-based glucose monitoring to optimize multiple daily injection (MDI) insulin therapy
- Lifestyle, activity, and nutrition effects on glucose in people with diabetes, pre-diabetes, obesity, or other conditions
- Evaluation of glucose variability in people with diabetes and pre-diabetes on different therapy regimens as measured by sensor-based glucose monitoring
- Evaluation of behavior and quality of life effects related to sensor-based glucose monitoring
- Sensor-based glucose monitoring for automated closed-loop control of blood glucose, also known as "artificial pancreas"
- Evaluation of meter- and computer-based informatics to guide diabetes therapy
- Evaluation of in-patient blood- and sensor-based glucose monitoring workflows, best practices and effectiveness

To receive materials to submit a research proposal, please e-mail a brief description of the study and support being requested, which may include product, financial, and/or technical support.

Send to:

adc_iis@abbott.com

Attention: Chair, Scientific Research Review Committee

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Proposals are received on an on-going basis, however typically we collect new proposals until September 15, 2018 for review for support in 2019, with decisions in November 2018. Support requests consisting only of FreeStyle Libre systems may be eligible for approval every 3 months.

Proposals for support should succinctly address the following items:

Section/item	**Description**
Background and rationale	Description of research question and justification for undertaking the trial and explanation for choice of any comparators.
Objectives	Specific objectives or hypotheses.
Trial design	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory).
Study setting	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected.
Eligibility criteria	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions.
Interventions	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered.
Outcomes	Primary, secondary, and other outcomes, including the specific measurement variable, analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended.
Participant timeline	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is recommended.
Sample size	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations.
Statistical methods	Statistical methods for analyzing primary and secondary outcomes.
Support requested	Describe support requested from Abbott in detail, including any materials (devices, sensors, strips), funding and/or technical support.

(Adapted from SPIRIT 2013 Checklist: http://www.spirit-statement.org/spirit-statement/)