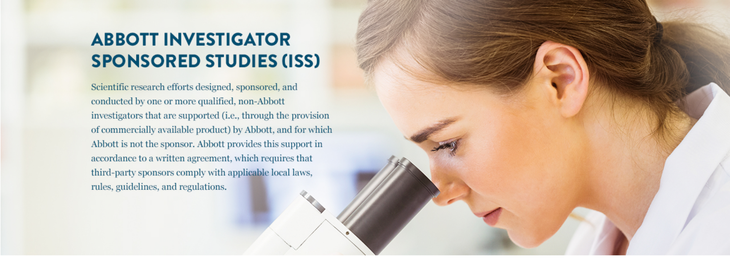
ABBOTT INVESTIGATOR SPONSORED STUDIES (ISS)

Scientific research efforts designed, sponsored, and conducted by one or more qualified, non-Abbott investigators that are supported (i.e., through the provision of commercially available product) by Abbott, and for which Abbott is not the sponsor. Abbott provides this support in accordance to a written agreement, which requires that third-party sponsors comply with applicable local laws, rules, guidelines, and regulations.



HOW DOES ABBOTT INVESTIGATOR SPONSORED STUDIES WORK?

TYPES OF RESEARCH ELIGIBLE FOR SUPPORT

- Clinical studies
- Observational studies: epidemiology or outcomes studies

ABBOTT'S REQUIREMENTS FOR INVESTIGATOR SPONSORED RESEARCH

Abbott is committed to high ethical and quality standards for investigator sponsored research. Proposals that demonstrate the following will be eligible for approval by the Abbott Scientific Research Review Committee:

- High ethical and scientific standards, and provides evidence that subject safety, rights, and well-being are not compromised
- Consistent with Abbott's overall business strategy
- Scientific need or interest that adds to the body of evidence and is not a duplication of research
- Only commercially available product, within country, is available for request
- Study completion within 12 months of contract execution; extensions possible with written justification
- Commitment to report the findings transparently and in a timely manner

QUALIFICATIONS OF SPONSOR INVESTIGATORS

- Evidence of research experience in the area of their proposal (e.g., documentation from local Ethics Committee or Institutional Review Boards, previous Abbott research experience in Abbott sponsored or investigator sponsored research, publications in peer-reviewed journals).
- Good medical standing (including no evidence of restrictions by a regulatory/government authority to undertake clinical research), as applicable by study type. If the principal investigator is not a physician, a sub-investigator who is a licensed physician must be included in the Investigator Sponsor's study team to provide medical oversight and evaluate study-related adverse events.

RESPONSIBILITIES OF INVESTIGATOR SPONSORS

Abbott is committed to supporting high-quality research endeavors. Abbott has documentation requirements of their Sponsor Investigators throughout the study's life cycle, which are as follows:

TIMELY RESPONSES

- Timely responses for updates/clarifications to scientific review committee

REQUIREMENTS FOR COMMERCIAL PRODUCT

DOCUMENTATION:

- Signed and dated investigator CV
- Executed clinical study agreement
- Finalized protocol
- Institutional Review Board/Ethics Committee (IRB/EC) review and approval documents (inclusive of all materials submitted—protocol, informed consent, subject materials, and advertisements [if applicable]). All approved materials must have version control.
- Evidence of review of Abbott Nutrition's Adverse Event Training Module

STUDY EXECUTION AND MAINTENANCE EXPECTATIONS

- For all clinical, prospective, or observational studies, Abbott encourages Investigator Sponsored Studies to be registered on the FDA's ClinicalTrials.gov or other trial registry in applicable country, prior to enrolling subjects.
- Abbott requires quarterly updates of the status of the study (enrollment, protocol changes, submissions to IRB/EC, deviations, serious adverse events, progress on analysis, and reporting of final results).
- If more than 2 sequential quarterly updates are not provided, or enrollment expectations are not met, the continued support of the study will be reviewed by the scientific research review committee and funding and/or product may be withheld, and study agreement may be terminated.

STUDY CLOSURE EXPECTATIONS

DOCUMENTATION:

- Final written report of study results (may be a manuscript, poster, abstract)

PUBLICATIONS:

- Any planned abstracts or manuscripts must be sent to Abbott in advance of submission in accordance with the study agreement.

KEY AREAS OF INTEREST*

ADULT NUTRITION

- Immunonutrition
- Wound healing
- Tolerance and GI health
- Malnutrition
- Diabetes
- Oncology

PEDIATRIC NUTRITION

- Tolerance
- Malnutrition
- Food allergies
- Real foods

HOW TO APPLY

Abbott accepts submissions through a web-based portal https://abbott-iis-portal.idea-point.com/Default.aspx.

SCIENTIFIC STUDY REVIEW MEETINGS

Abbott conducts multidisciplinary Scientific Research Review Committee meetings twice per month.