Mission

The DePuy Synthes Investigator Initiated Study (IIS) program is aimed at advancing scientific knowledge through the support of research proposals from investigators.

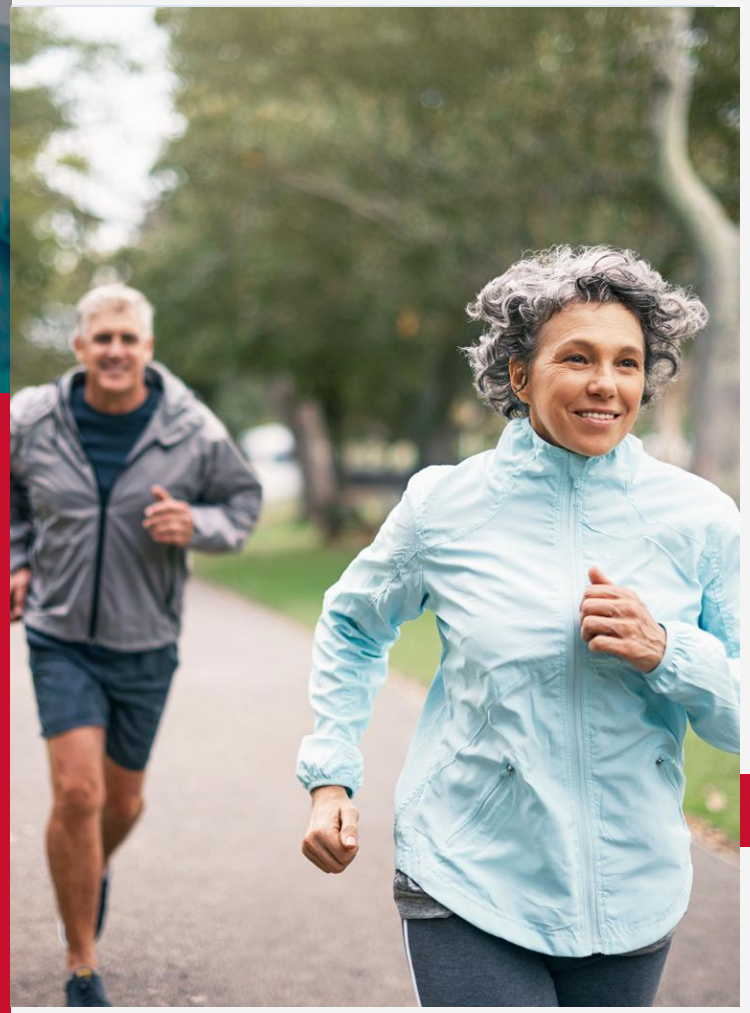
DePuy Synthes has developed the online submission process in order to ensure a systematic approach to receiving, reviewing and supporting research proposals. This global program includes a competitive review which allows DePuy Synthes to select the best and most scientifically valid proposals to support. In order for the internal review process to run smoothly, it is important that the submitter complete all fields as accurately as possible. This will ensure a comprehensive and fair review by our internal experts.

Who do I Contact With Questions?

During the submission process, your primary contact will always be your DePuy Synthes Clinical Research Representative. Upon approval, the IIS coordinator will be your primary contact.
If you have any questions or comments regarding the investigator initiated study submission process, please contact our mailbox:

RA-DPYUS-IISApplicat@ITS.JNJ.com

DePuy Synthes



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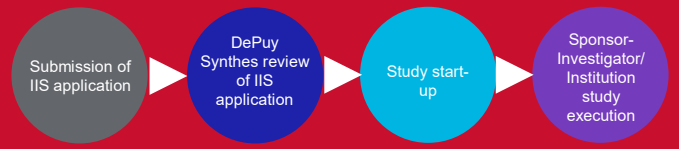
Investigator Initiated Study Program

IIS Process Overview



What is an IIS?

- An IIS is a research effort in which the investigator designs and implements the study and the investigator or the institution acts as the Sponsor-Investigator/Institution
- As the Sponsor-Investigator/Institution, the investigator assumes all responsibilities for complying with applicable regulatory requirements
- IIS support may be in the form of product and/or funding

What is the role of the Sponsor-Investigator/Institution?

- The Sponsor-Investigator/Institution, as the sponsor, must ensure that the study is conducted in accordance with Good Clinical Practice (GCP) for Medical Devices: ICH GCP E6 and ISO 14155, and all applicable regulatory requirements
- The Sponsor-Investigator/Institution assumes all responsibilities for complying with applicable legal and regulatory requirements

What is the role of DePuy Synthes?

- Review the IIS application for potential approval
- Communicate decision to Sponsor-Investigator/Institution
- Contract with Sponsor-Investigator/Institution and provide financial support and/or product

What is the IIS Submission and Review Process?

Step 1: Submission of IIS Application

- For additional information and to submit an application, visit: https://jnjmd-iis-portal.idea-point.com
- Refer to 'Research Opportunities' to view our Requests for Proposals (RFPs)
- Complete all fields as accurately as possible, including an itemized budget
- Upload your curriculum vitae (CV)

Step 2: DePuy Synthes Review of IIS Application

- A decision is based on various criteria such as the scientific merit of the research, study design, timelines and feasibility, extent of support being requested, fit with DePuy Synthes strategic research priorities, fit with other ongoing or planned studies
- Your DePuy Synthes Clinical Research Representative will contact you to communicate the decision and provide a formal decision letter
- If your IIS application is approved, the process will move to Step 3

Step 3: Study Start-Up

- Contract negotiations will begin per Sponsor's institutional policy
- The study is activated upon execution of contract and Institutional Review Board (IRB) or Ethics Committee (EC) approval

Log into your account at any time to see the status of your proposal: https://jnjmd-iis-portal.idea-point.com

Step 4: Sponsor-Investigator/Institution Responsibilities for Study Execution

- Following the approved study protocol
- Ensuring the quality of the study data
- Adhering to all applicable laws and regulations
- Adhering to DePuy Synthes safety reporting requirements
- Providing DePuy Synthes with regular status updates
- Providing DePuy Synthes with a final study report and/or publication according to contractual agreement

Note: Approval of the IIS concept does not indicate approval of full requested budget.

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