Proposal Form



Investigator Initiated Study

Proposal Form

Background

Straumann is a global leader in implant and restorative dentistry and oral tissue regeneration. For more than half a century, our company has focused on scientific research and innovation, which has helped to establish and expand the fields of modern dental implantology and regeneration. By following our commitment to “simply doing more for dental professionals”, we aim to deliver superior solutions that enable practitioners to provide the best possible care to patients.

Close collaboration with dental professionals who use our products has also been a hallmark of Straumann’s success. To continue this tradition and facilitate the process of turning concepts into solutions, Straumann invites our customers to submit study proposals, which are received, reviewed and given feedback by a dedicated Research Screening Committee.

The goal of the research project is to publish an article in an international peer-reviewed journal.

Procedure

* To submit your Study Proposal, email the completed Proposal Form in English, along with your CV,
to research-screening@straumann.com (for US applicants: clinical.nam@straumann.com)
* Only completed forms will be considered

Review Process

The Research Screening Committee is composed of Straumann experts pursuing responsibilities within various departments of the company. The Research Screening Committee meets on a regular basis to review all incoming applications. A decision on your proposal will be communicated within three months after submission.

Please acknowledge that Straumann is free to accept your request or to decide not to support it.

Further information can be obtained from:

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| Institut Straumann AG | For US applicants: |
| Clinical Research | Clinical Research Department |
| Peter Merian Weg 12 | Straumann USA, LLC |
| CH-4052 Basel Switzerlandresearch-screening@straumann.com | 60 Minuteman Road Andover, MA 01810clinical.nam@straumann.com |

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| **Application Date :** |       |

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| **Study Team:** |
| Primary Investigator (PI):      Co-Investigators:      Study nurse/ Coordinator:      (if applicable)Institution and Department:       |
| Contact details primary investigator (lead study center):Street:       Postal Code:      City:       Country:      State (for US addresses):      Email:       Phone:       |
| Additional study centers:      |

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| **Study Overview:** |
| Study Title:       |
| Rationale of study:(what is the reason for performing this study?) |       |
| Study hypothesis:(Formulate only one hypothesis) |       |
| Type of study: | [ ]  In vitro / Bench test [ ]  Animal study  | [ ]  Clinical study [ ]  Case series  |
| Study design:(in case of a clinical study) | [ ]  Prospective [ ]  Controlled [ ]  Randomized  | [ ]  Retrospective [ ]  Single-arm (single cohort) [ ]  Non-randomized  |
| Field: | [ ]  Implants [ ]  Prosthetics Other:        | [ ]  Regenerative [ ]  CAD/CAM  |
| Number of patients /animals/samples | Total:       Per group:       |
| Sample size calculation:(if applicable) | Calculated number (without drop-outs):      Rationale:       |
| Study Device (Product Name): |       |
| Control Device (Product Name):  |       |

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| **Study Budget:** |
| Total study budget: (provide reasonable detail) |       |
| Expected financial contribution from Straumann: (detailed specification) |       |

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| **Requested material support** (Straumann products only): |
| Article description | Article number | Quantity |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
| Discs for in vitro studies: | Type:        | ∅ 15 mm:       | ∅ 5 mm:       |

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| **Study Details:** |
| Primary endpoint:      |
| Secondary endpoints:      |
| Indication:      |
| Materials and Methods (for clinical study: include planned study schedule, inclusion/exclusion criteria):      |
| Statistical methods:      |

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| **Planned Study Dates:** |
| Estimated study start: (for clinical study: estimated date of ethical committee approval) |       |
| Duration of patient recruitment:(clinical study only) |       |
| Estimated study end:(for clinical study: estimated date of last patient follow-up) |       |
| Date of first draft publication:(date of draft manuscript provided to Straumann for review)  |       |
| Publications & Presentations (describe number, content and target journals of planned publications and congress contributions):      |

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| **Experience of primary investigator:** |
| Number of published articles in international peer-reviewed journals **(as PI)**: |       |
| Specify three most relevant currently ongoing studies you are running **(as PI or co-investigator)**:  |
| No.  | Type | Title | Industry partner |
| 1) |       |       |       |
| 2) |       |       |       |
| 3) |       |       |       |
| ISO/GCP training performed (certificate available)? | [ ]  Yes [ ]  No |
| CV provided together with this proposal (mandatory for first time applicants)? | [ ]  Yes [ ]  No |

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| **Monitoring, data management and analysis:** |
| Who performs monitoring (only applicable for clinical studies)? |       |
| Who manages the data (e.g. creates and maintains the database)? |       |
| Who performs the statistical analysis? |       |
| Who writes the publication(s)? |       |