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Application Date (dd/mm/yyyy

Study Team/ Applicant/ Co-Applicant(s)

Name Position

Institution and Department

Contact Details (Study Center)

Street Postal Code

City Country

State (for US addresses)

Phone Email

Experience

Primary Investigator (PI)

Experience as a Physician (100 characters)

Experience with Clinical Studies ○ Yes ○ No

If yes, please specify (as PI? Study Team?)

Experience with Medartis products ○ Yes ○ No

Publications and Presentations

GCP Certificate

Yes (dd/mm/yyyy) ○ No

Study Center(s) ○ Single-center ○ Multi-center

Name

Institute

Address

Name

Institute

Address

Study

(Working) Title

Synopsis / Rationale

Background (300 characters)

Main Hypothesis

Aim

Type of Study ...

Study Design ...

In case of Prospective Clinical Study: randomized ○ Yes ○ No

Indication ... ...

Study and Control Device (product name and number)

Number of Patients / Sample Size Calculation

Primary Outcome Parameter(s)

Secondary Outcome Parameter(s)

Material and Methods (incl. schedule / timeline, inclusion / exclusion criteria)

Statistic Plan (which tests are to be performed on primary / secondary outcome parameters? By whom?)

Follow-Up of Patients ○ Bony Union ○ Complications (clinical vs. hardware-related) ○ Functional Outcomes ○ QoL Other

Overall Timeline for Follow-Up

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Study Budget

Total (please attach detailed budget)

Expected Support / Contribution from Medartis AG
(please note: external and independent service providers are contracted for compliance reasons where applicable)

○ Financial ○ Hardware & Training ○ Scientific Writing ○ Study Protocol
○ Statistical Analysis Other

Planned Study Dates

Estimated Time for Patient Recruitment
Estimated Time for Overall Study Conduct
Expected Date of Publication

Quality Control Systems / Monitoring / Data Management

○ CRF ○ eCRF
Monitoring Plan
% Source Data Verification
Data Management Plan
Archiving
Data Security and Protection

Date
Signature

Please note

After evaluation of your project and a positive decision to support your work, we may require some of the following accompanying documents:

- Complete and version-controlled study protocol
- Ethics / IRB approval (incl. communication)
- Statistic plan (if prospective clinical study)
- Data management plan (incl. access regulation, audit trail, archiving, etc.)
- Quality management (incl. Monitoring Plan if prospective clinical study)
- Up-to-date CVs of all principal and co-investigators
- Up-to-date GCP certificates of all principal and co-investigators (if prospective clinical study)
- Copy of (e)CRF (if prospective clinical study)
- Patient information / Informed consent procedure (if prospective clinical study)
- Handling of AE / SAE (if prospective clinical study)
- Final report / publication (and annual report, if prospective clinical study)

By submitting the above application form, you accept the “Terms and Conditions” linked here.