Ein Bild, das Zeichnung enthält.

Automatisch generierte Beschreibung

Please return to:

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**Proposal for retrospective clinical trials of the PDWP**

**Protocol Title:**

**Investigator(s):**

**Institution:**

**Study Design:**

**❒** Retrospective registry based (Med A/Med B)

**❒** With additional data collection

**❒** Paper based questionnaire

**❒** Online questionnairebased (Survey Monkey et al)

**❒** Collaboration with other working parties/groups

**Which:**

**Study Rationale:**

**Research hypothesis:**

**Study Phases:**

*(i.e. Primary registry data survey, additional data collection, analysis et al)*

**Timeline:**

*(to be completed by applicant and data office in Paris)*

Primary registry data collection:

Interim analysis:

Additional data collection:

Data processing and analysis:

Manuscript preparation:

Final manuscript preparation:

Final manuscript review by data office and WP chair:

**Study Procedure:**

**Study Population:**

**Research Variables:**

**Primary Objective:**

**Secondary Objective(s):**

**Primary Endpoint (measure of outcome):**

**Secondary Endpoint(s:**

**Inclusion Criteria:**

**Exclusion Criteria:**

**Sample size calculation:**

**Expected enrolment:**

**Statistical Design:**

**Recruitment:**

**❒** by center **❒** by country

**❒** by registry **❒** by working party

**Budget Estimate:**

**Financing:**

**Industrial Collaboration: ❒** yes **❒** no

*Upon approval of the proposal by the WP the timeline has to be followed. If timelines exceed substantial and reflect a lack of activity towards the goal of a timely completion of the project, the WP chair reserves the right to reassign the project to a different investigator, primarily within the group of designated collaborators.*