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 questionnaire based (Survey Monkey et al)
- ☐ Collaboration with other working parties/groups
  - Which:

Study Rationale:

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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.