

ARCTIC-I Appendix 2 – Timeline

Overall timeline

The following project plan has been conceived:

Recruitment of centres	ongoing throughout 2021
Writing of protocol including appendices	until September 2020
First IRB submission	October 2020 in Munich
Patient enrolment	1 st quarter of 2021 to end of 2022
Data base cleaning in parallel with data entry	3 rd quarter of 2021 until end of 2022
Publication of detailed statistical analysis plan	1 st half of 2022
Statistical analysis after database lock	1 st half of 2023
Manuscript writing, submission process	2 nd and 3 rd quarter of 2023
Acceptance of the manuscript is the target line of the project	

Sequence of tasks for individual centre

This table lists the tasks in chronological order and links them to protocol sections and appendices.

Task	Protocol	Appendix
Register online on the ESAIC website	n/a	n/a
Participate in the pre-study enquiry (online)	-	3
Check with NC that informed consent forms and interview for endpoint assessment are available in national language	-	6A-D, 9B
Seek approval of the protocol and appendices from the IRB	-	-
Send documentation of IRB approval to ESAIC	-	4
Train study team with regard to Informed Consent	8.2	6A-C
Train study team for screening, enrolment and data capture	8.7	7, 8, 9A-B, 10
Determine beginning of the enrolment phase (rules see below)	n/a	n/a
Active study period (screening, enrolment, informed consent, and data capture including follow-up on day 90)	8.2 8.7	7, 8, 6A-D 9A-B, 10
Enter data in eCRF, answer data cleaning queries	-	-
Send end of study form to ESAIC	12.1	11

Scheduling of the patient enrolment phase for individual centres

Minimum length of the interval “first patient in to last patient in” per site is six months, but can be prolonged by full months up to nine months. For the enrolment period, the following rules apply:

- Beginning (‘first patient in’) at the earliest in 1st quarter of 2021
- Minimum duration of enrolment phase (‘first patient in’ to ‘last patient in’) is 6 months
- Centres can optionally extend enrolment by full months up to 9 months
- Active study period per site (‘first patient in’ to ‘last patient out’) is duration of enrolment plus three months (due to collection of primary endpoint at 90 days)