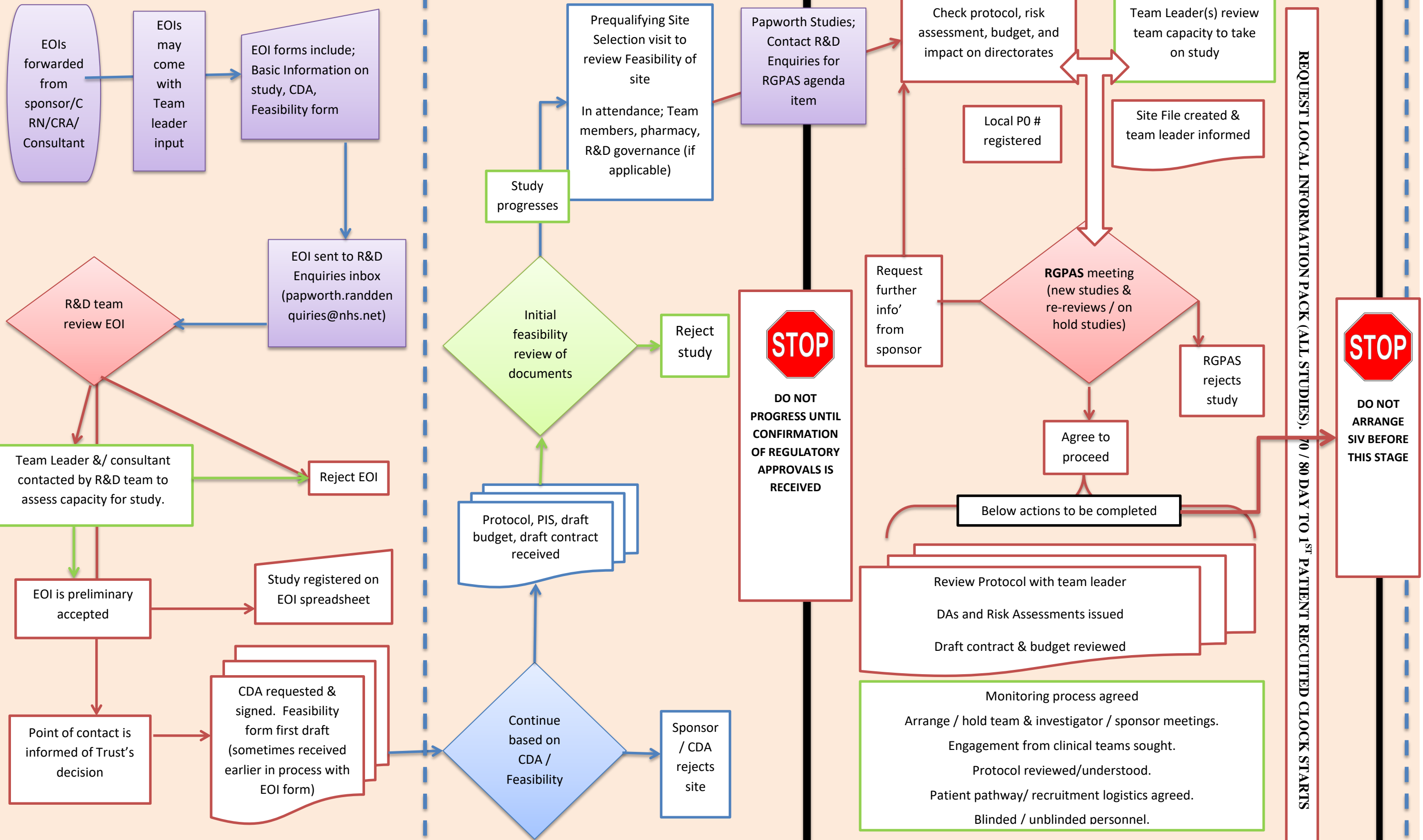


EOI STAGE **SITE SELECTION STAGE** **FEASIBILITY STAGE**



REQUEST LOCAL INFORMATION PACK (ALL STUDIES). 70 / 80 DAY TO 1ST PATIENT RECRUITED CLOCK STARTS

START UP STAGE

STUDY COMMENCES



CVs & GCP certificates checked

Actions from RGPAS checked

Directorate Authorisations Agreed

Budget Agreed in principle

Initial Review of contract – agreed in principle

Training on EDC, Study specifics

Final Review of Documents

Pathology registration completed

Pathways finalised

R&D team issue (Amber light) for SIV to start

Staff training held during SIV

SIV held with sponsor

Delegation log signed

Capacity & Capability notification issued

Contract & Budgets signed

Invoice for set-up fees

Prepare study specific monthly invoicing requirements

Costs loaded onto EDGE

Sponsor green light requirements completed

Sponsor green light given

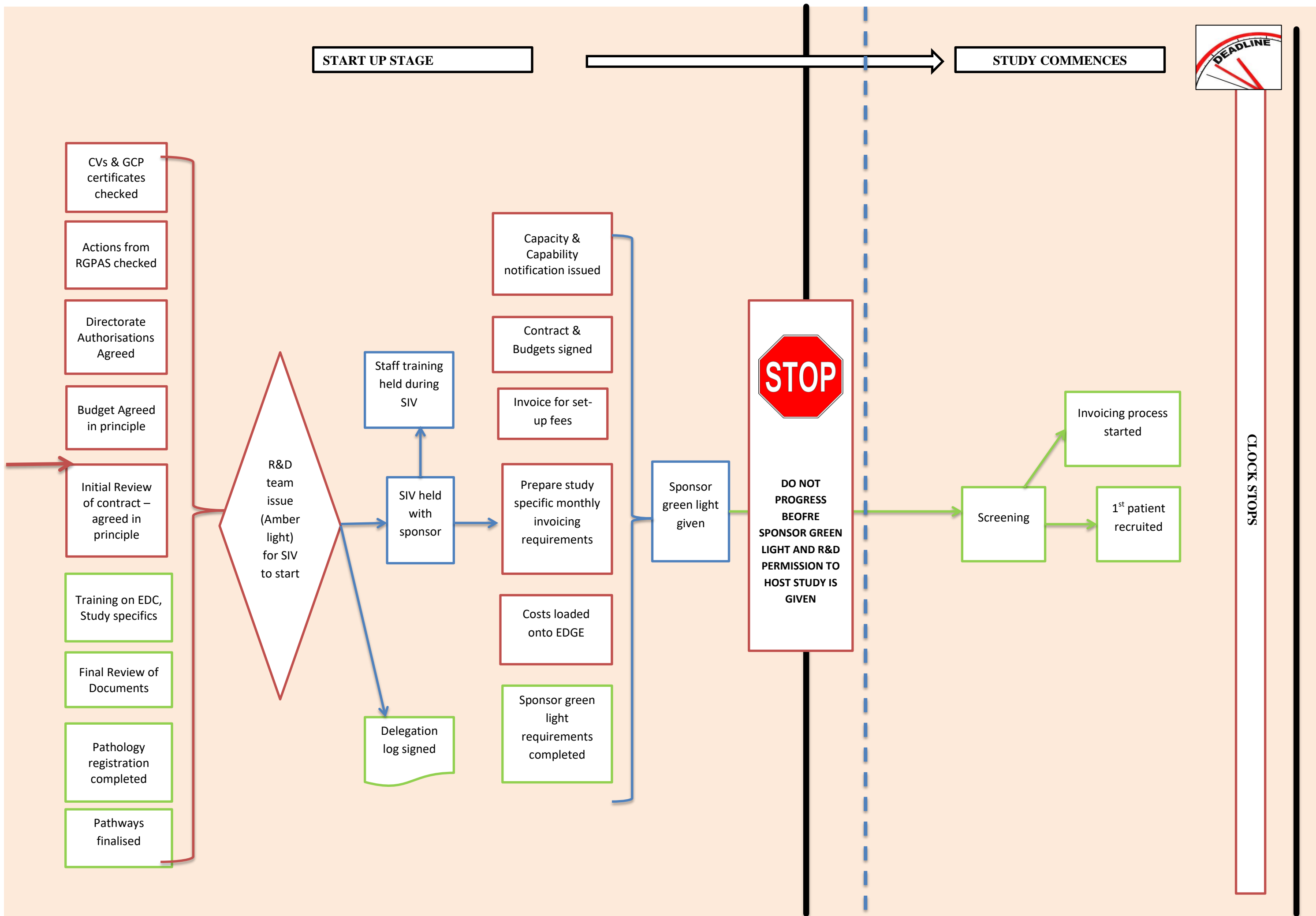
STOP
DO NOT PROGRESS BEFORE SPONSOR GREEN LIGHT AND R&D PERMISSION TO HOST STUDY IS GIVEN

Screening

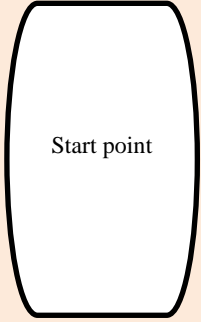
Invoicing process started

1st patient recruited

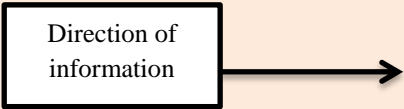
CLOCK STOPS



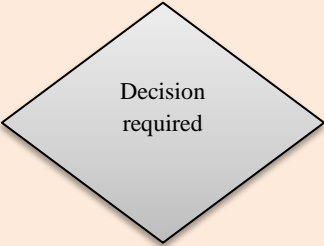
Key



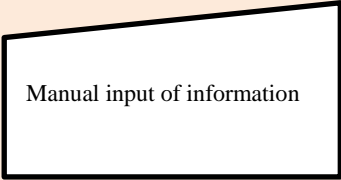
Start point



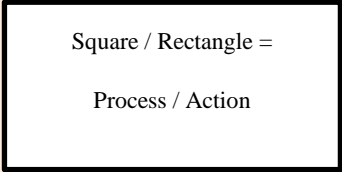
Direction of information



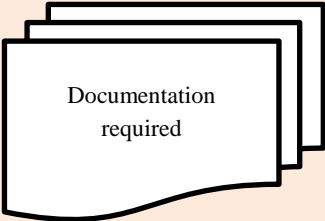
Decision required



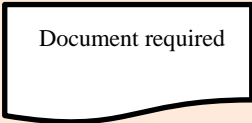
Manual input of information



Square / Rectangle =
Process / Action



Documentation required

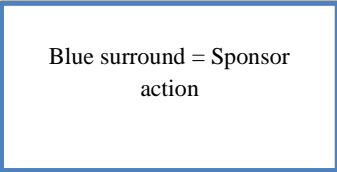


Document required

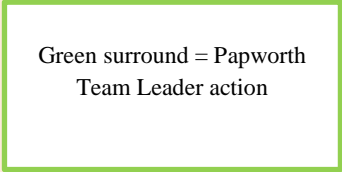
Milestone – Do Not Progress Until All Other
Actions Have Been Completed

End of Stage

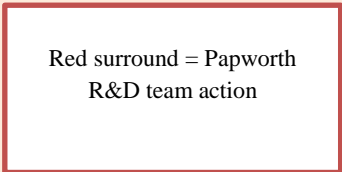
- EOI – Expression of Interest
- R&D – Research & Development
- RGPAS – R&D Governance committee meeting
- PIS – Patient Information Sheet
- ICF – Informed consent form
- CDA – Confidential Disclosure Agreement
- CRN – Clinical Research Network ('the Network')
- CRA – Clinical Research Associate



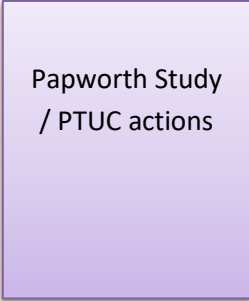
Blue surround = Sponsor
action



Green surround = Papworth
Team Leader action



Red surround = Papworth
R&D team action



Papworth Study
/ PTUC actions