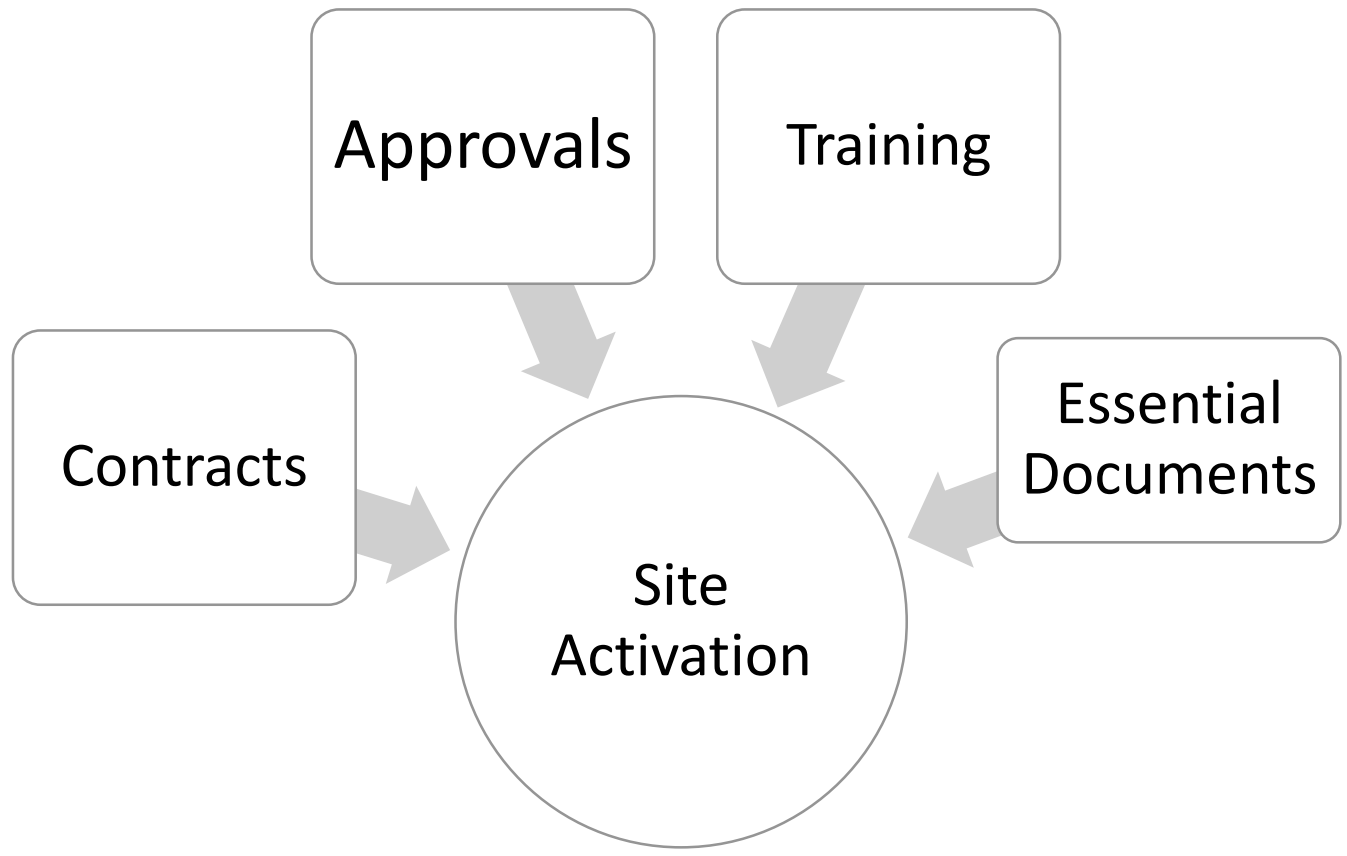
FAST Therapy Trial

SITE ACTIVATION PROCESS



CONTRACTS

- Study Agreements (RCT) (SickKids and National Coordinating Centre (NCC))
- Site Study Agreements (RCT) (NCC & sites)
- Financial Agreements (SickKids & sites)
- Data collection agreement for Registry (SickKids & sites)

APPROVALS

- Regulatory (National Sponsor)
- Central Ethics (National Sponsor if centralized)
- Local ethics (sites)

TRAINING

- For all staff delegated to perform study procedures
- Good Clinical Practice (GCP) – where applicable Citi-GCP training required (Canada & US)
- Study Training
- Institutional (as required by your institution)

ESSENTIAL DOCS

- Contracts (clinical trial, data transfer, financial)
- Regulatory approvals
- Ethics approvals
- Staff Training documentation
- Staff qualifications (medical license, CV's)
- Budget
- Pharmacy agreement
- Master Binder
- Procedures & SOPs

ACTIVATION

- Sponsor meeting to review essential documents (Study Coordinator)
- Study Training (study team & PI)
- Site Activation once all required training and documents are in place!