**STUDY START-UP CHECKLIST –**

**Clinical team**

**JT#**: Click or tap here to enter text. **PI**: Click or tap here to enter text.

**Sponsor**: Click or tap here to enter text.

**Protocol Title**: Click or tap here to enter text.

**Instructions**: Please use the checklist throughout the study start-up phase of the trial. Note, certain sections contain tasks specific to their trial type and location(s) of trial activation.

# **Pre-Multidisciplinary Group (MDG) Committee Meeting** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm CDA was signed by JCRI business operations   Click or tap to enter a date.

2. Confirm completion of feasibility questionnaire   Click or tap to enter a date.

3. Pharmacy feasibility review (ePRO)   Click or tap to enter a date.

4. Confirm Pre-Site Visit was conducted with sponsor and PI   Click or tap to enter a date.

5. Confirm receipt of finalized protocol   Click or tap to enter a date.

6. Confirm site selection by the sponsor   Click or tap to enter a date.

7. Schedule review for MDG/Regional Research Committee (RRC) meeting (only needs to be reviewed at RRC if site specific PI did not vote at Enterprise Wide (EW) MDG meeting) [Send agenda 48 hours in advance]

Click or tap to enter a date.

8. Add trial to PDL/tracker   Click or tap to enter a date.

9. Confirm sponsor approval for Multi-Site   Click or tap to enter a date.

Including:

a. One PI for all sites\*   Click or tap to enter a date.

b. Confirm and document all site numbers for each site

Click or tap to enter a date.

c. One contract and budget   Click or tap to enter a date.

d. IP shipment directly to each site   Click or tap to enter a date.

e. CRA monitoring at each site   Click or tap to enter a date.

f. Study supplies shipment directly at each site   Click or tap to enter a date.

g. Availability of non-English translated consents (inclusive of populations at Regional Research Sites (RRS))   Click or tap to enter a date.

h. Resource guide   Click or tap to enter a date.

\*PI oversight plan available to share with sponsor

10. Verify if an NCTN Trial with IP shipped from PMB that an investigator at the site has the site as their shipping address *(if needed work with Pam Touchstone to update the shipping address of the investigator on their CTEP account)*

Click or tap to enter a date.

# **MDG Committee Meeting** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm MDG approval from majority of voting members

Click or tap to enter a date.

2. Confirm RRS participation   Click or tap to enter a date.

3. Confirm enrollment goal per site   Click or tap to enter a date.

4. Confirm Institutional PI and site PI   Click or tap to enter a date.

5. If RRC did not vote at E-W MDG meeting, PI &/or MDG PM attends RRC MDG and presents trial for vote

Click or tap to enter a date.

6. Complete MDG REDCap entry   Click or tap to enter a date.

7. Send MDG approval/disapproval notification e-mail [PI, MDG Leader, RRC Leader, CTO Directors, CTO Regulatory Managers, Budgets/Contracts, Site Lead, Coordinator (if applicable)]

Click or tap to enter a date.

8. Create protocol record in JeffTrial (see JeffTrial guidance document)

\*Add key personnel for each site to JeffTrial staff list

Click or tap to enter a date.

9. Update JeffTrial with MDG and RRC meeting outcomes (if applicable)

Click or tap to enter a date.

10. Submit protocol and MDG approval to JCRI for calendar build

Click or tap to enter a date.

11. Identify program assignment and submit for CRLC review and determination

Click or tap to enter a date.

12. Finalize MDG meeting minutes and obtain MDG Lead signature

Click or tap to enter a date.

13. Complete MDG Priority Form and obtain signature from MDG lead

Click or tap to enter a date.

14. Update disease map   Click or tap to enter a date.

# **Protocol Feasibility committee (PFC)** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Complete PFC submission form   Click or tap to enter a date.

Including:

1. Identification of primary coordinator   Click or tap to enter a date.
2. Identification of data manager   Click or tap to enter a date.
3. Ancillary department involvement   Click or tap to enter a date.
4. Identification of any specialized study labs and equipment

Click or tap to enter a date.

2. Prepare and send PFC submission packet (PFC submission form, pharmacy manual, imaging manual, laboratory manual, protocol)

Click or tap to enter a date.

3. Share PFC submission packet with RRC   Click or tap to enter a date.

4. Present protocol at assigned PFC meeting and RRC PFC meeting (if applicable)

Click or tap to enter a date.

5. Confirm PFC approval   Click or tap to enter a date.

6. RRS PM: Update JeffTrial with meeting approval details and send PFC approval e-mail (if applicable)

Click or tap to enter a date.

7. Complete Radiology Feasibility (if applicable)   Click or tap to enter a date.

8. Complete Institutional Biosafety Committee (IBC) initial submission (if applicable)   Click or tap to enter a date.

9. Complete Value Analysis Committee submission (if applicable)

Click or tap to enter a date.

# **Pre-IRB Submission (When handled by Research Support Services Reg Ops)** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm receipt of Radiology Manual   Click or tap to enter a date.

2. Confirm approval from Radiology Feasibility if applicable (needed for IRB submission)

Click or tap to enter a date.

3. Confirm IBC approval if applicable (needed for IRB submission)   Click or tap to enter a date.

4. Confirm Value Analysis Committee approval by regulatory if applicable (needed for IRB submission)

Click or tap to enter a date.

5. Confirm regulatory coordinator is assigned   Click or tap to enter a date.

6. Confirm submission packet to regulatory (Disease map, PRMC questions, Priority form, Radiology/IBC/Value Analysis Committee approval(s) as applicable)

Click or tap to enter a date.

7. For NCTN studies, begin Imaging Radiation Oncology Core (CORE) credentialing if applicable   Click or tap to enter a date.

8. For NCTN Begin surgical credentialing if applicable   Click or tap to enter a date.

9. Confirm list of study staff with regulatory in JeffTrial (for NCTN trials also review DTL)

Click or tap to enter a date.

10. Review ICF (check for any inconsistencies and for financials)   Click or tap to enter a date.

11. Confirm if patient reimbursement/payment is provided

Click or tap to enter a date.

12. Identify IRB of Record (Jefferson or Central)   Click or tap to enter a date.

1. If Central IRB, find out from sponsor if Jefferson has to submit SAE and/or deviations OR if sponsor will submit on our behalf   Click or tap to enter a date.
2. If Jefferson does not submit, identify sponsor staff responsible and ensure access to central IRB system

Click or tap to enter a date.

1. Identify reporting requirements of the trial by sponsor and IRB

Click or tap to enter a date.

13. Confirm Value Analysis Committee approval if applicable (needed for IRB submission)

Click or tap to enter a date.

14. Confirm submission packet to regulatory (Disease map, PRMC questions, Priority form, Radiology/IBC/Value Analysis Committee approval(s) as applicable)

Click or tap to enter a date.

15. For NCTN studies, begin Imaging Radiation Oncology Core (CORE) credentialing if applicable   Click or tap to enter a date.

16. Begin surgical credentialing if applicable   Click or tap to enter a date.

# **Pharmacy/Drug** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm receipt of pharmacy manual   Click or tap to enter a date.

2. Create and submit Beacon Build   Click or tap to enter a date.

3. Confirm IDS & CRC has Interactive Voice Response System (IVRS) access, if needed   Click or tap to enter a date.

4. Confirm how to order study drug   Click or tap to enter a date.

5. Confirm receipt of study drug prior to activation, if applicable   Click or tap to enter a date.

6. For NCTN studies, confirm Pharmaceutical Management Branch (PMB) account & a shipping Investigator is available on site for each site participating site

Click or tap to enter a date.

7. Confirm if IP is hazardous, if so, confirm use of Jefferson CSTD   Click or tap to enter a date.

# **iMAGING** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm receipt of imaging manual   Click or tap to enter a date.

2. Complete Radiology Feasibility Form   Click or tap to enter a date.

3. Confirm access to imaging upload system (eg. Bioclinica, Paraxel, Triad etc.)   Click or tap to enter a date.

4. Confirm radiology approval   Click or tap to enter a date.

# **Laboratory** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm receipt of lab manual   Click or tap to enter a date.

2. Confirm SKCC-PK-PD & RRS Team can process research labs or if other lab support is needed   Click or tap to enter a date.

3. Confirm storage requirements (eg. Batch shipping)   Click or tap to enter a date.

4. Confirm receipt of lab kits at all sites   Click or tap to enter a date.

5. Confirm completion of PKPD/RRS lab requisition sheets   Click or tap to enter a date.

6. Confirm access to Lab site or portal   Click or tap to enter a date.

7. Confirm tissue request/shipping process/labels   Click or tap to enter a date.

# **Data Management and Coordination** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. If IIT, confirm creation of database (REDCap)   Click or tap to enter a date.

2. If sponsor/NCTN trial, confirm necessary staff have access to Electronic Data Capture system (EDC)   Click or tap to enter a date.

3. If sponsor/NCTN trial, confirm necessary staff have completed EDC training   Click or tap to enter a date.

4. Create progress notes   Click or tap to enter a date.

5. Develop EPIC research progress note   Click or tap to enter a date.

6. Create source documents   Click or tap to enter a date.

7. Confirm imaging portal access   Click or tap to enter a date.

8. Confirm QOL/Questionnaire portal access   Click or tap to enter a date.

9. Create documents for in-service   Click or tap to enter a date.

# **Miscellaneous** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm access to all applicable protocol systems   Click or tap to enter a date.

2. Upload documents to shared drive (AE log, deviation log, sponsor specific forms for reporting SAE’s, screening and enrollment logs, source documents)   Click or tap to enter a date.

3. Confirm arrival of sponsor equipment for each site participating in Trial (EKG machine, BP cuff, etc.)   Click or tap to enter a date.

4. Confirm equipment functions properly   Click or tap to enter a date.

5. Equipment inspected by BioMed and site-specific engineering departments for other sites

Click or tap to enter a date.

6. Training of staff on operation of equipment   Click or tap to enter a date.

7. Confirm pathology/biopsy request process   Click or tap to enter a date.

# **Financial Contract** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm Calendar Build is complete in JeffTrial   Click or tap to enter a date.

2. Confirm budget and contract are finalized   Click or tap to enter a date.

3. Verify Clinical Trial Agreement (CTA) is signed by PI   Click or tap to enter a date.

4. Confirm grant/account number was assigned and pushed to EPIC   Click or tap to enter a date.

5. Check contract for competitive or set enrollment (if set enrollment make sure PM monitors accrual and reaches out to regulatory for accrual amendment as needed)   Click or tap to enter a date.

6. Review Visit Payment Tracker (VPT)/set up VPT review and training with JCRI   Click or tap to enter a date.

7. If NCTN trial, check funding page/OPEN system   Click or tap to enter a date.

8. Confirm participant payment account (eg. ClinCard) is set up, payment cards have been received, and staff have been trained to use payment portal and distribute payment cards.   Click or tap to enter a date.

# **Site Initiation Visit (SIV)** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Schedule SIV with participating sites   Click or tap to enter a date.

2. Create SIV slides (if necessary)   Click or tap to enter a date.

3. Send SIV confirmation and agenda (study team, nursing, regulatory, QAE, IDS, PKPD Lab, etc.)   Click or tap to enter a date.

4. Confirm SIV was completed   Click or tap to enter a date.

5. Schedule in-service with applicable clinical nursing team (eg. Infusion nurses, radiation oncology nurses, inpatient team, etc.)   Click or tap to enter a date.

# **Activation** COMPLETE **|** N/A **|** Date Completed (if applicable)

1. Confirm ready to activate with sponsor (greenlight) for each site and inform regulatory of sponsor greenlight   Click or tap to enter a date.

2. Confirm ready to activate internally (all boxes are checked) for each site   Click or tap to enter a date.

3. Send activation e-mail   Click or tap to enter a date.

4. Confirm regulatory updated JeffTrial record to “open to accrual”   Click or tap to enter a date.

5. Complete in-service/training for nursing staff as needed   Click or tap to enter a date.

6. Confirm trial populates in EPIC for clinicians to choose as a pathway as applicable   Click or tap to enter a date.

**Completed by:**

**Printed Name Signature Date**