



CIRM Expectations for Translational Stage Project Managers

Role Description

A project manager (PM) under a CIRM TRAN award is responsible for proactively driving planning and execution of the project strategy to advance the Therapeutic, Diagnostic, Device or Tool to the next stage of product development. In partnership with the PI, this will involve oversight of project plan execution through the close monitoring of critical path activities and the creation of contingency plans to resolve issues and achieve deliverables. Key responsibilities include:

- Facilitate effective planning with the Team to define key activities with appropriate scheduling and budgeting.
- Drive planning and execution of the Team activities to meet project deliverables through facilitating effective meeting management, transparent team communication, problem solving, efficient decision making, proactive risk management and conflict resolution.
- Enable advancement to next stage of product development (e.g. pre-IND filing and FDA engagement for a candidate therapeutic) through an effective program review process; navigate regulatory compliance and project risks.

CIRM expects that an individual in the PM position will have a demonstrated track record with these operational elements *before* award launch. **Typical CV Requirements include:**

- B.S. or B.A degree, preferably in relevant scientific field, or the equivalent.
- Multiple years of relevant post-graduate experience,
- Drug and/or Medical Device development & commercialization experience is desirable
- Knowledge of Project Management best practices and software tools for communication, scheduling, budget & resource planning, team building and risk management
- Project Management Professional (PMP) certification considered an asset
- Solid knowledge and understanding of relevant FDA (or CMS) regulatory guidance documents (for Therapeutic, Device, Diagnostic projects)
- Demonstrated ability to work independently to manage complex projects with multiple priorities in a team-based environment
- Excellent oral and written communication skills (listening, negotiation, presentation, organizational and relationship-building) required

Budget

CIRM estimates that typical PM support for the skills and experience described above costs \$120,000-\$160,000 for the duration of the TRAN award (30 months). If external PM support needs to be subcontracted by the project, CIRM estimates an additional \$30,000 in travel and expenses.

QuintilesIMS Stem Cell Center PM services

QuintilesIMS has been awarded by CIRM to create the [Stem Cell Center \(SCC\)](#), which offers PM services. PM services offered by the SCC are not subject to 35% minimum effort for TRAN projects. Applicants that plan to use SCC PM services need to include a letter of support from QuintilesIMS in their application. The SCC can be contacted at StemCellCenter@quintilesims.com.