

QuintilesIMS Stem Cell Center

Driving stem cell development from candidate identification through market authorization

What is the QuintilesIMS Stem Cell Center?

The focus in Regenerative Medicine (RMx) is changing from bench medicine to clinic-commercial success. RMx faces many headwinds: complex preclinical/nonclinical models, constrained clinical manufacturing capacity, limited clinical sites with RMx experience, shifting regulatory landscape and an unclear pathway for pricing and market access. Working in close collaboration with the California Institute for Regenerative Medicine (CIRM), and our alliance partners, City of Hope for manufacturing and CMC support and Charles River Laboratories for preclinical/nonclinical research, the Stem Cell Center provides a comprehensive suite of services to tackle the most pressing challenges in the field.

Who we are

We are a dedicated team focused on accelerating preclinical/clinical development, and commercialization of stem cell and cellular therapies for companies and research institutions. We leverage the scale, expertise, strategic insight and operational excellence of QuintilesIMS and our alliance partners address the unique challenges faced by sponsor organizations.

What we do

We provide end-to-end solutions and targeted services to advance assets from candidate identification through market authorization. We leverage the expertise of world class organizations – QuintilesIMS, City of Hope, and Charles River Laboratories – to bring the best clinical development, cell manufacturing and preclinical/nonclinical experts, and operational capabilities to our clients.

By bringing all these capabilities together backed by our long track record of success and hands-on experience, we can improve your preclinical/nonclinical and clinical development pathways, optimize your manufacturing and reduce your time to and increase your probability of success in the market.

Who we help

We offer support to all organizations involved in the stem cell and cellular therapy space regardless of development stage and source of funding. Our customized solutions provide the flexibility needed to increase the probability of success of your cell therapy independent of your organization's size or experience.

Our core offerings



Why should you engage with the Stem Cell Center?

The Stem Cell Center accelerates development from candidate identification through market authorization by leveraging four key differentiators:

Four value-add levers to accelerate development



End-to-end and customized solutions Integrated services that provide a one stop shop and optimize efficiency throughout asset development	Strategic advice to operational delivery Strategic planning, backed by deep industry expertise, to improve the probability of clinical and commercial success
Best and next practices Cross-functional teams that leverage scientific, clinical, regulatory, and commercial experience to drive innovative solutions	Coordinated, partnered delivery Partnerships with premier organizations to deliver seamless program management across the product development lifecycle

Benefits of engagement for all our clients

The Stem Cell Center can help you maximize the impact to:

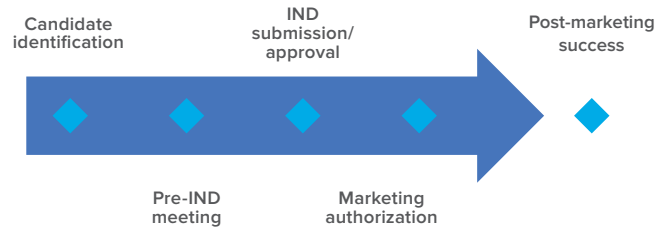
- Secure grant funding – up to \$20M – for preclinical/nonclinical studies, manufacturing optimization, process development, regulatory strategy and operations, clinical trial execution and market access strategy
- Leverage best practices and recent precedents in planning and design of your study development plans
- Improve your probability to successfully reach your next milestone

Benefits of engagement for CIRM applicants

- Access to unique insight to optimize grant application and budget development
- Preferred pricing and priority status for delivery of services related to grant awards

When should you engage with the Stem Cell Center?

Engaging the Stem Cell Center at any point during development can help advance your program.



Are you eligible for a CIRM translational or clinical grant?

In addition to our strategic and operational services, we can help you determine your eligibility for CIRM grants and optimize the development of your application.

CIRM translational and clinical grants can be used to support:

- Pivotal IND-enabling preclinical/nonclinical services – pharmacology and toxicology studies, process development, manufacturing
- IND-filing and clinical start-up services – regulatory documentation, IND development and filing services, protocol development, IB generation
- Clinical conduct services – clinical operations, safety monitoring, patient recruitment
- Commercial services – health economics and outcomes research studies, real-world evidence strategy, pricing and market access assessments
- Project management services – project management support to coordinate efforts across project stakeholders, ensure project stays on track and meet its milestones

Your research may be eligible for CIRM funding, independent of your organization being based in or out of California.

CONTACT US

QuintilesIMS Stem Cell Center

+1 844 399 5698

10188 Telesis Court, Suite 400, San Diego, CA 92121

www.quintilesims.com

StemCellCenter@quintilesims.com