

Preclinical Translation: A Partnership between USC Stevens, CHLA OTT and CS-CTSI

The SC CTSI Preclinical Translation and Regulatory Support Program (PCT RS) helps biomedical researchers translate and accelerate novel therapeutics, diagnostics, and medical devices into pre-clinical development. PCT RS's goal is to increase the translation of research discoveries into products that benefit health and health care.

The main path for this translation is via commercialization. To this end, PCT RS partners with USC Stevens and CHLA Office of Technology Transfer (OTT) to provide a full array of services needed for preclinical development in an academic setting. Within this partnership:

- **USC Stevens** and **CHLA OTT** provide services, resources and training related to intellectual property, commercialization, marketing and licensing.
- **PCT RS** provides scientific assessment, access to technical resources, regulatory support, project management support, and some direct funds for project development.

PCT RS Services Offered by the Preclinical Translation Team:

Initial Assessment and Advice: In an initial in-person meeting, the PCT RS team provides a preliminary assessment of the translational potential of each project. The team advises on: (1) time and resources required for translation, (2) competitive landscape, and (3) major hurdles and how they might be overcome. Following the in-person meeting, the PCT RS team provides investigators with a written summary of the assessment and next steps. Next steps include actions to position those projects with good translation potential for support by the PCT RS team or referral to other USC resources, as appropriate.

In-Depth Translational Assessment: Projects with promising translational potential upon initial assessment will be incorporated in the preclinical project portfolio and receive an in-depth written translational product development strategy, summarizing the product's opportunity and risks, and identifying a product development strategy. This translational strategy incorporates feedback from regulatory experts on regulatory strategy, industry advisors on product positioning and risks, and either USC Stevens or CHLA OTT on intellectual property and commercialization potential.

The product development strategy identifies: (1) current stage of product development (2) project opportunity-risk analysis including review of data, markets and IP (3) a project plan highlighting project needs and development milestones (e.g. R&D needs such as preclinical tox, chemistry etc.), (4) regulatory requirements for market approval, (5) project planning where project needs are mapped to position the product for commercialization.

Panel Review: Upon completion of the in-depth assessment, each project will be reviewed by a panel of experts who will advise the PCT RS team whether it should provide continued services, whether alternative avenues exist to support the project, or whether the project should be discontinued.

Continuing Services: Each project selected by the PCT RS team after panel review will receive customized services based on the projects' unique needs outlined in the product development strategy. PCT RS services and resources include the following and are listed according to the increasing involvement required by PCT RS staff:

- 1. Connect scientific and clinical investigators with complementary expertise**
- 2. Provide regulatory consultation to define product development pathways**
- 3. Identify and recruit expert consultants (including coordinating contracts)**
 - a. Coordination with USC Stevens Institute and CHLA OTT for commercialization & intellectual property (IP) plan
 - b. Coordination with other SC CTSI centers (eg. Biostats, Human Studies)
 - c. Sourcing external service providers (contract labs)
 - d. Providing industry advisor consultation for product development strategy
- 4. Identify resources for project funding**
 - a. Referral for best strategic fit for intramural funding, review of applications
 - b. Panel review participation for intramural funding programs
 - c. Direct funding through PCT RS Advance Fund
 - d. Referrals to industry funding paths
 - e. Identification of appropriate grant opportunities
- 5. Provide project management**
 - a. Developing project plans, milestone development, and timelines
 - b. Sourcing cross-functional team members (manufacturing, PK, tox etc)
 - c. Managing teams to execute project plan and manage budget

Services Offered by USC Stevens and CHLA OTT

USC Stevens and CHLA OTT contribute intellectual property (IP) management, commercial analysis, marketing and licensing of the technologies disclosed to the respective offices for all fields of use.

Through its New Ventures team, USC Stevens further offers translation support, including mentoring and connections to industry resources to provide guidance on product development, positioning, and go to market strategies for developing start-up companies. USC Stevens provides funding support for selected projects with high translational potential determined with input from an external advisory committee.

USC Stevens contributes to the PCT RS's in-depth translational assessment through scoping of potential intellectual property protection and commercial value. USC Stevens provides these additional services for projects with commercial potential.

1. Technology advancement & licensing: life cycle management

- a. Commercial feasibility, IP analysis and strategy
 - i. Patentability assessment (Prior art searches, completeness of written description; Data strength
 - ii. Competitive market analysis
 - iii. External review and feedback
- b. Intellectual Property protection/strategy
 - i. Prosecution of patent applications and portfolio management
- c. Business development
 - i. Targeted and non-targeted marketing
 - ii. Licensing

2. Translational funding programs

- a. Gap-funding (Ideas Empowered, USC-JNJ TIPP, Coulter Program)
- b. Mentoring (pitch preparation, business plan development, market research)
- c. Legal office hours
- d. Expert review panels and feedback

3. New ventures: startup support

- a. Formation of Management Teams: access to experienced entrepreneur to assist with start-up development, and assistance with formation of management team
- b. Product positioning, and business plan assistance
- c. Targeted marketing to investors: outreach to venture firms and other investors
- d. External industry review panels for sourcing of high impact projects

For further information:

SC CTSI Preclinical Translation (PCT RS): Christine Matheson, matheson@usc.edu, <http://sc-ctsi.org/>

USC Stevens: Annette Kleiser, akleiser@stevens.usc.edu, stevens.usc.edu

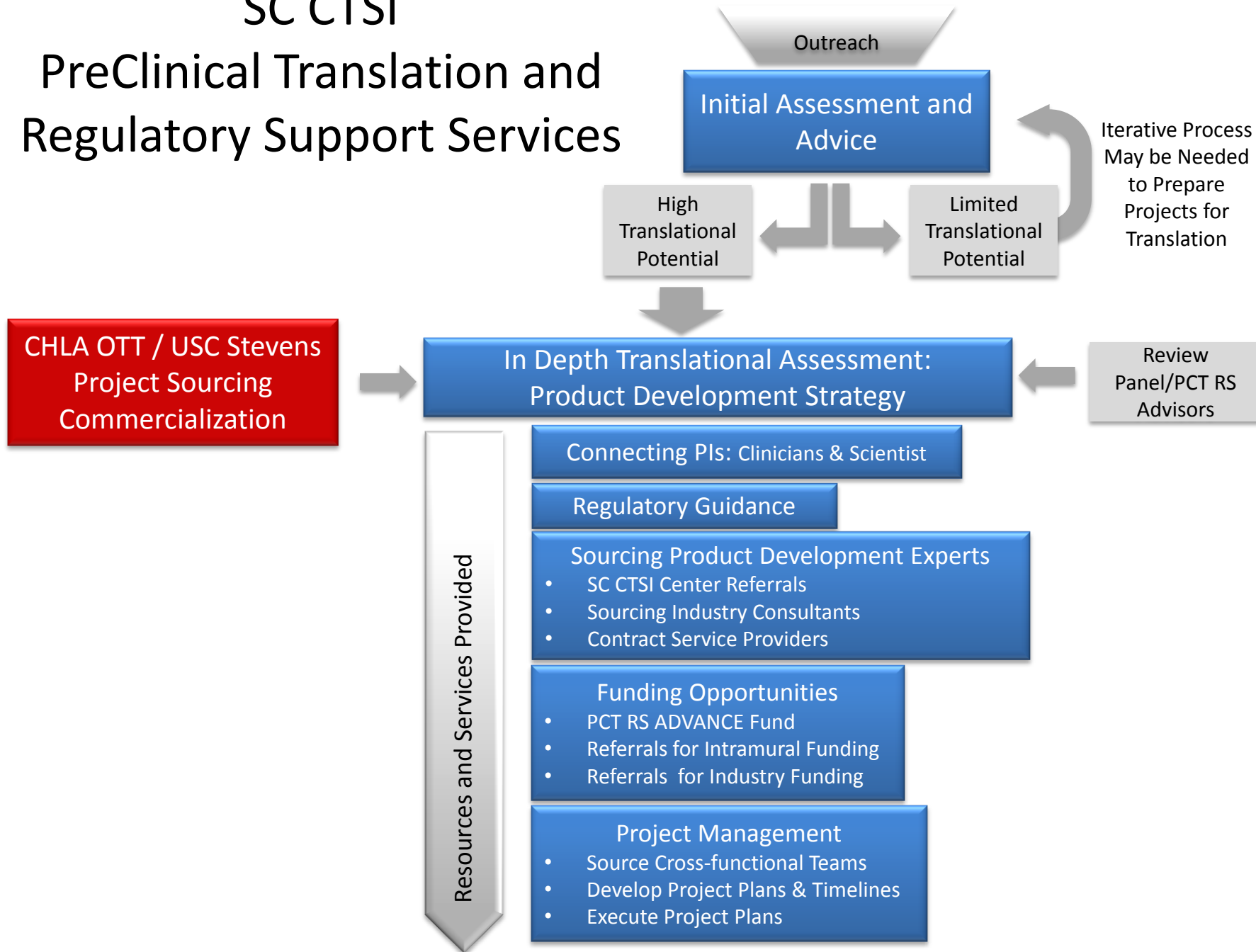
CHLA Office of Technology Transfer: Jessica

Rousset, jrousset@chla.usc.edu, www.CHLA.org/TechTransfer

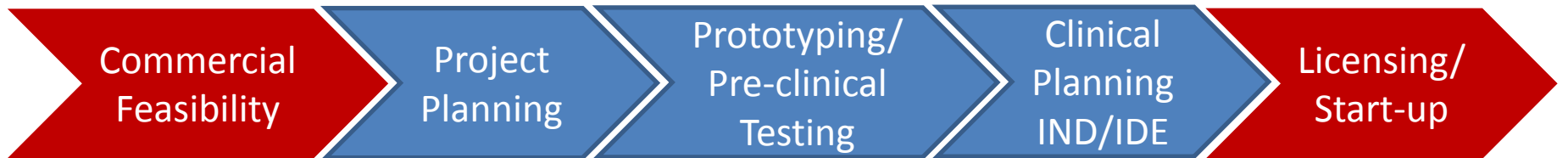
Service	Support Unit
Initial Assessment and Advice	PCT RS
In-Depth Translational Assessment	PCT RS/USC Stevens/CHLA OTT
Connecting PIs: Matching Clinicians with Scientists	PCT RS
Regulatory Guidance	PCT RS
Sourcing Product Development Experts (contractors and consultants)	PCT RS
Referrals for Funding Opportunities, PCT RS Advance Fund	PCT RS
Project Management	PCT RS
Commercial Feasibility, IP Analysis and Strategy	USC Stevens/CHLA OTT
Intellectual Property Protection/Strategy	USC Stevens/CHLA OTT
Business Development	USC Stevens/CHLA OTT
Translational Funding Programs (Ideas Empowered, JNJ Partnership)	USC Stevens
New Ventures; start up support	USC Stevens/CHLA OTT

SC CTSI

PreClinical Translation and Regulatory Support Services





SC CTSI PreClinical Translation and Regulatory Support Partnership with USC Stevens/CHLA OTT



IP assessment
IP management
Initial market analysis

Connecting PIs
Regulatory Guidance
Prof Services Network
Product Development
Project Management
PCT Advance Fund

Translational Programs
Prof Services Network
Mentor Network
Biz plan/pitch deck
Team Development
Fundraising
COI Navigation
Marketing/Licensing

 USC Stevens / CHLA OTT
 SC CTSI/PCT RS