

Disease Team Therapy Development III

RFA 13-01: CIRM Disease Team Therapy Development III Awards

The purpose of CIRM's Disease Team Therapy Development III initiative is to advance early clinical development of novel therapies derived from or targeting stem cells, potentially offering unique benefit with well-considered risk to persons with disease or serious injury. Disease Team Therapy Development III Awards will support actively managed teams to conduct milestone-driven preclinical and clinical development.

The objective of a Disease Team Therapy Development III award will be to achieve, in 4 years or less, the completion of an early clinical trial under an Investigational New Drug (IND) application filed with the Food and Drug Administration (FDA).

Proposed projects must complete one or more of the following:

- A Phase 1 clinical study to demonstrate preliminary safety, assess measures of biological/clinical activity in humans, and determine a range of safe doses to be studied in subsequent trials
- A Phase 2 clinical study to evaluate both safety and efficacy of the candidate therapeutic.
- For CIRM-funded Early Translational awardees only, file a complete and well-supported IND

Please see the RFA for full details.

RFA 13-01: CIRM Disease Team Therapy Development III Awards [pdf]

(Amended 2/11/13 - Section V.A on page 7 of the RFA was amended to make a correction to the eligible therapeutic candidates.)

- Appendix A – Loan Information [pdf]
- Appendix B – MRC (United Kingdom) Collaboration Information [pdf]
- Appendix C – MOST (China) Collaboration Information [pdf]
- Appendix D – NIH (United States) Collaboration Information [pdf]
- Appendix E – IATA (Andalusia, Spain) Collaboration Information [pdf]
- Appendix F – CIRM Translational Portfolio [pdf]

CIRM conducted a webinar on Wednesday February 6, 2013 to provide information regarding RFAs 13-01 including tips to potential applicants, an overview of the application process and questions from applicants. **Archived materials from this webinar are available for your reference at: <https://www.cirm.ca.gov/our-funding/webinar-cirm-disease-team-therapy-development-iii-awards>**

Participants are encouraged to submit questions prior to February 6, 2013 through the Webex registration process or via email at DT3Questions@cirm.ca.gov. Questions may also be submitted in writing during the live webinar via the Webex functionality. If you have any technical issues, please call Webex support at 866.229.3239.

Application Process

Submission of an application for the CIRM Disease Team Therapy Development III Awards RFA involves a two-step process. An eligible applicant must first submit a Letter of Intent (LOI) to CIRM following the instructions below. In the second step of the process, eligible applicants will submit a full application. The Principal Investigator and the project proposed in the application must be the same as those described in the LOI; otherwise, the application is deemed ineligible.

LOI Submission Instructions:

The Letter of Intent (LOI) must be submitted via the CIRM Grants Management Portal, as follows:

1. Go to the Grants Management Portal (https://grants.cirm.ca.gov/login/upgrade_browser) and log in with your existing CIRM

Username and Password. If you do not have a Username, click on the "New User" link and follow the instructions to create a CIRM Username and password.

2. After logging in, your home page will display a list of open RFAs or LOIs. Click on the "**Start a Letter of Intent**" link located to the right of the section labeled "**RFA 13-01 CIRM Disease Team Therapy Development III Awards: Letter of Intent**".
3. Complete the LOI by following the posted instructions.
4. The "**Done with Letter of Intent**" button becomes enabled when all sections are complete. Select this button to complete your LOI submission. Once this button has been selected, you will no longer be able to make changes to your LOI.
5. To ensure the process is complete, go back to your home page and check for "**RFA 13-01 CIRM Disease Team Therapy Development III Awards**" in the section titled "**Your Submitted Applications**".
6. The LOI must be received by CIRM no later than 5:00 pm (PDT) on March 13, 2013 via the CIRM Grants Management Portal. No exceptions to this deadline will be made.

Application Instructions and Forms

Application forms will be available on the CIRM website <https://grants.cirm.ca.gov> in mid-March. Only those applicants that submitted an LOI that was accepted by CIRM may submit an application. Applicants will be notified if their LOI was NOT accepted.

A description of all application components can be found within the RFA. To assist in your preparation for the Disease Team Therapy Development application, sample documents of key application components are provided at the end of the RFA.

The application for RFA 13-01 consists of up to nine parts:

- Part A – Application information (web based)
- Part B – Disease Team Therapy Development III proposal (MS Word template)
- Part C – Biographical sketches for key personnel (MS Word template)
- Part D – Activity Based Budget (MS Excel template)
- Part E – FDA Correspondence
- Part F – Clinical Protocol
- Part G – Investigator Brochure
- Part H – Copies of authorization for cross reference of master files
- Part I – Licenses and agreements (e.g. MTAs)

All applicable parts of the Application for RFA 13-01: CIRM Disease Team Therapy Development III Awards must be submitted together and received by CIRM no later than 5:00 pm PDT on May 15, 2013 via the CIRM Grants Management Portal. It is the applicant's responsibility to meet this deadline. No exceptions will be made.

Schedule of CIRM Deadlines and Reviews	Date
LOI due	5:00 pm (PDT), March 13, 2013
Applications due	5:00 pm (PDT), May 15, 2013
Scientific Review of Applications by Grants Working Group (GWG)	September 2013
Review and Approval by ICOC	December, 2013
Earliest Funding of Awards	Q1, 2014

Contacts

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For information about the review process:

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Phone: (415) 396-9103 Appendix A – Loan Information

ICOC approval:

Dec 12, 2013

Source URL: <https://www.cirm.ca.gov/our-funding/research-rfas/disease-team-therapy-development-iii>