CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Memorandum

To: Members of the ICOC
From: Gil Sambrano, Vice President, Portfolio Development and Review
Rosa Canet-Avilés, Chief Science Officer
Re: Examples of Proposed Pre-Submission Forms
Date: March 27, 2025

CIRM is proposing to utilize a pre-submission process for selecting projects that are best aligned with the strategic goals of the PDEV and DISC4 funding opportunities and to narrow the number of applications that advance to Grants Working Group (GWG) panel review. For illustrative purposes, we are providing you an outline for each program that summarizes the information to be collected within an online pre-submission form. These outlines serve as a reference for creating an interactive, electronic pre-submission form within the Grants Management System (GMS). Prospective applicants access the online forms by using or creating a system login and password in the GMS. The actual online forms are organized for ease of use and provide instructions for completing and submitting. The final process and specific evaluation criteria will be described in the respective Program Announcements so that applicants will have clarity on pre-submission form components and selection process. Pre-submission is designed to gather sufficient information to perform eligibility assessments, evaluate the pre-submissions for program fit and discourage pre-submissions that are incomplete, ineligible, or poorly aligned with program objectives.

DISC4 Pre-submission Form: Overview

DISC4 pre-submissions will be completed through CIRM's online grant portal and includes a brief online intake section, including a project questionnaire, and an uploaded proposal document. The form and upload are designed to gather sufficient information to perform eligibility assessments, evaluate the pre-submissions for program fit and discourage pre-submissions that are incomplete, ineligible, or poorly aligned with program objectives.

The pre-submission form is organized into the following sections:

Section	Format	Description	Usage*
Eligibility	Online form	Required certifications that the project and applicant team meet CIRM eligibility requirements.	Eligibility
Core Team	Online form	Entry of Core Team members for the project (contact information, effort, description of role) and eligibility certification checklist	Informational, Eligibility
Project Information	Online form/ check-list	Entry of project title and selection of key words to describe proposed research	Informational
Questionnaire	Online form	Brief description of proposal responsiveness to program objective and preferences	Evaluated
Proposal	Document upload	Three-page overview of project objectives, major aims, research design, rationale, and proposed budget	Evaluated

*CIRM will utilize various pre-submission components as follows:

- Eligibility: Will be used for internal confirmation that the project meets CIRM eligibility requirements
- Evaluated: Will be used for pre-submission evaluations to determine responsiveness to the program, including program preferences
- Informational: Will be used for internal informational use

Pre-submission Instructions

CIRM DISC4 Program

Thank you for your interest in CIRM's DISC4 funding opportunity. The table below provides an overview of the DISC4 program, the DISC4 2026 timeline, key information sources, and contact information.

AWARD OVERVIEW	
Award Objective	Support comprehensive discovery research across a diverse range of diseases and bottlenecks that will accelerate the development of potential therapeutics and biomarkers in regenerative medicine.

Scope of DISC4 Award	Expansive, cross-disciplinary and integrated studies led by large collaborative teams applying a range of technologies and approaches to address knowledge gaps or bottlenecks in our understanding of human diseases.
Preferences	Review the DISC4 PA for the preference topic relevant to this funding cycle.

SCHEDULES AND DEADLINES Subject to change with notice	
Pre-submission Due	Pre-submissions must be fully submitted by 2:00pm (PDT/PST) on Monday, June 16, 2025
Application Due Date	Approximately 60 days post pre-submission deadline
Grants Working Group (GWG) Review	Approximately 120 days post application submission deadline
Award Approval	Approximately 150 days post application submission deadline
Start Date	Must be ready to start award activities within 120 days of award approval

CONTACT AND ADDITIONAL RESOURCES

DISC4 Program Announcement <link>

CIRM Funding Opportunities: Common Requirements and Definitions <link>

For additional information on the program, pre-submissions, or applications, contact discovery@cirm.ca.gov. <link>

For questions related to the review and approval of applications, contact review@cirm.ca.gov. <link>

DISC4 Pre-submissions

This is a **pre-submission form** to be used by CIRM to identify the most responsive preliminary proposals to be invited to submit a full DISC4 application in the upcoming award cycle.

You must read the DISC4 Program Announcement (PA) <link> and CIRM Funding Opportunities: Common Requirements and Definitions <link> carefully to understand the eligibility criteria, scope, budget limits, allowable activities, and all other requirements for this funding opportunity before proceeding. The PA also describes CIRM's selection and award administration processes for DISC4. DISC4 awards are subject to the Grants Administration Policy <link>, the Intellectual Property and Revenue Sharing Requirements and additional regulations that can be found in our Grant Regulations. <link>

An investigator may pre-submit as PI for only one DISC4 project and may pre-submit as a member of the core team (PI or Co-I) for up to two DISC4 projects.

Please download and populate the current DISC4 pre-submission templates from the "Document Uploads" section of this form. Templates from a different CIRM program or prior DISC4 review are not appropriate.

Eligibility

DISC4 projects must fully satisfy several eligibility requirements that are described in the DISC4 PA <link> and CIRM Funding Opportunities: Common Requirements and Definitions <link>. These include a requirement that the PI and at least four Co-Is must be at California-based (CA-based) organizations at the time of application. Additionally, at least one Co-I must be based at a different organization than the PI. CIRM has a specific definition of a CA-based organization as follows:

A "California Organization" is a for-profit or non-profit organization or is a California-domiciled wholly owned subsidiary of a non-California organization (any entity that does not qualify as a California Organization) that meets all of the following criteria:

1. Employment and Payroll:

a. Employs at least one W-2 employee; and

b. More than 50% of its W-2 employees, whether part-time or full-time, who are paid in any manner (e.g., wage, salary, commission, equity), must be domiciled full-time in California and be required to file California state income taxes due to their employment with the organization.

2. Management of Award Activities: The Principal Investigator (PI) must be physically located in California while overseeing all project activities.

3. Intellectual Property Rights: In the case of a California-domiciled wholly owned subsidiary of a non-California organization, the subsidiary must retain exclusive rights to any intellectual property arising out of the CIRM-funded project as well as any pre-existing IP rights held by the parent organization.

Eligibility Certification

[ ] <required certification> I, the PI, certify that I have read and understood the eligibility criteria in the DISC4 PA <link> and CIRM General Eligibility Requirements and Applicant Resources <link>, and to the best of my knowledge will be able to meet these criteria in the full application (if invited).

Complete and Accurate

[ ] <required certification> I acknowledge that in order to submit the pre-submission all required components of the pre-submission must be complete and may not contain any false or inaccurate information.

Core Team

Each application must be led by a core team of one (1) CA-based Principal Investigator (PI) and at least four (4) CA-based Co-Investigators (Co-I). At least one Co-I must be based at a different organization than the PI.

Section	Field	Instructions	Format
Core Team	Principal Investigator (PI)	The PI is the individual, designated by the Grantee, responsible for the scientific or technical aspects of the CIRM-funded Project or Activity and for its management. For DISC4, the PI must commit at least 15 percent effort to the project.	Name: Title: Institution: Department: Address: Phone: Email: Role on Project: Percent Effort: Role Description: (450 characters)
	Co-Investigators (Co-Is)	For a DISC4 project, a Co-I is one of four or more, non-PI team members	List here all Co-I as defined above: Name:

		committing at least 10 percent effort to the project. Individuals who do not meet the definition of Co-I should not be identified here.	Title: Institution: Department: Address: Phone: Email: Role on Project: Percent Effort: Role Description: (450 characters)

Team Certifications

[ ] <required certification> I, the PI, certify that the core team (Principal Investigator (PI) and Co-Investigators) is multi-institutional and includes at least five (5) investigators based in California.

[ ] <required certification> I, the PI, certify that, to the best of my knowledge, I will be able to commit at least 15 percent effort to this project, if funded, for the term of the project.

[ ] <required certification> I, the PI, certify that, the Co-Investigators listed above have agreed to participate in the Co-Investigator role for this DISC4 project, if funded, with at least 10 percent effort committed to the project for the term of the project.

[ ] <required certification> I, the PI, certify that if invited to submit a full application, my project team must include members with specific relevant expertise including a) an experienced data project manager; b) a team member with clinical expertise; 3) a team member with industry/translational expertise; and 4) a team member with computational or bioinformatics expertise.

Project Information

Section	Instructions	Format
Project Title	Provide a brief title for your proposed project.	Text entry (120 characters)
Stem Cell Use	If applicable, select the human stem/progenitor cell type(s) to be used in the project. If not applicable, select N/A.	Checkbox, required [ ] Adult hematopoietic stem cells [ ] Neural stem cells, non-embryonic [ ] Adult mesenchymal stem cells [ ] Cancer stem cells [ ] Embryonic stem cells [ ] Induced pluripotent stem cells [ ] Other stem cell type [ ] N/A
Data Types	Select the data types that will be generated and/or analyzed during the proposed project or select 'other'.	Checkbox, required [ ] Single-cell omics [ ] Bulk -omics [ ] Transcriptomics

		[ ] Proteomics [ ] Metabolomics [ ] Lipidomics [ ] Epigenomics [ ] Flow/Mass Cytometry [ ] Structural Biology [ ] Microscopy [ ] Medical Records [ ] Medical Imaging [ ] Patient/Caregiver/Provider Reports [ ] Electrophysiology [ ] Behavior Studies [ ] Other
Disease Areas	Select at least one disease area most likely to be impacted by a successful outcome of the proposed research or select 'other'. If not applicable, select N/A.	Checkbox, required [ ] Bone & Cartilage Disorders [ ] Brain Cancers [ ] Cancers, Multiple Types/sites [ ] Cardiovascular Disorders [ ] Eye/Vision Disorders, Neurological [ ] Eye/Vision Disorders, Non-neurological [ ] Hematological Malignancies [ ] Hematology Disorders [ ] Infection/Infectious Disease [ ] Metabolic Disorders [ ] Muscle Disorders [ ] Neurological Disorders [ ] Respiratory Disorders [ ] Skin Disorders [ ] Solid Tumors [ ] Other [ ] N/A
Neurological Disease Area	If you selected "Neurological Disorder" above, select the most relevant type of neurological disorder	[ ] Neurodegenerative Disorders [ ] Neuroinjuries [ ] Neurodevelopmental Disorders [ ] Neuropsychiatric Disorders [ ] Other Neurological Disorders
Bottlenecks	Select at least one technical bottleneck most likely to be impacted by a successful outcome of the proposed project or	Checkbox, required [ ] Biomarker Discovery [ ] Cell/Tissue Targeting [ ] Data Science, Computational Approaches [ ] Epigenetic Editing

	select 'other'. If not applicable, select N/A.	[ ] Extending or Validating the Applicability of Regenerative Medicine Discoveries to Underserved Populations [ ] Gene Editing Technologies [ ] Gene Therapy Delivery Methods [ ] Gene Therapy Vectors [ ] Human Cell / Tissue Atlas [ ] Imaging Tools [ ] Immunogenicity, Toxicity [ ] Mechanisms of Disease to Enable Rational Design of Stem Cell/Gene Therapy Treatments [ ] Reverse Translation [ ] Target Discovery [ ] Other [ ] N/A
Additional Keywords	If you checked 'other' for any key word type above, enter up to ten key words to describe outcomes (e.g., specialized data types), disease areas, or bottlenecks directly relevant to the proposed project, separated by commas.	Text box (150 characters]

Questionnaire

Please answer the following questions for consideration of your pre-submission form:

Instructions	Format
DISC4 awards are open to all research topics or disease indications without restriction however, specific preference topics are prioritized each cycle. Describe how your proposal aligns with the current cycle's neurodegeneration preference topic. (Please see DISC4 Program Announcement <link> for further details)	Text entry (1500 characters)
Highlight the major stem-cell based approaches and/or genetic research approaches proposed. Describe the aspects of these approaches that are innovative relative to current/historical approaches.	Text entry (1500 characters)
Describe how this proposal integrates multiple disciplines, frameworks or approaches, and how that creates unique synergy.	Text entry (1500 characters)
This opportunity funds foundational research with a focus on disease biology. Describe the disease or disease areas in which this research will most likely have an impact. Describe how you will ensure that any novel therapeutic or biomarker targets and that result from this effort will progress towards translational/clinical use.	Text entry (1500 characters)

Document Upload: Proposal

Instructions: This document is the template document for the DISC4 Award pre-submission. Please use this document to provide a brief overview for the proposed research.

Requirements:

- Up to 3 pages; excess pages will be discarded
- Up to 3 figures overall; excess figures will be discarded.

Your response should include the following:

1. **Overall Objective and Major Aims:** succinctly state the overall project objective and list all major aims that will be pursued to achieve this objective.
2. **Outline of Research Plan:** Outline the proposed research project, including brief description with key approaches and expected timelines if possible. The expected project outcome and proposed aims should be logical and likely to be achieved within the allowed project period.
3. **Rationale and Supporting Data:** Summarize the scientific rationale for the proposed research including the most relevant preliminary data and other findings (e.g. published results) that support the concepts or major approaches proposed
4. **Budget Information**: Provide a brief description of the project's funding needs, including how they will be distributed across core team investigators and years. (Recommended: 1-2 paragraphs or table)

PDEV Pre-submission Form: Overview

PDEV pre-submissions will be completed through CIRM's online grant portal and includes an online form and a single uploaded proposal document to verify candidate eligibility and confirm project readiness. The form and document are designed to gather sufficient information to perform eligibility assessments, evaluate the pre-submissions for program fit and discourage pre-submissions that are incomplete, ineligible, or poorly aligned with program objectives.

The pre-submission form is organized into the following sections:

Section	Format	Description	Usage*
Eligibility	Online form	Required certifications that the project and applicant team meet CIRM eligibility requirements.	Eligibility
Personnel	Online form	Entry of PI and Key Personnel information (contact information, effort, description of role)	Informational, Eligibility
Project Information Questionnaire	Online form/ check-list	Entry of candidate, disease, and project information	Informational, Eligibility, Evaluated (refer to specific sections)
Pre-submission Upload	Document upload	Three-page overview of candidate eligibility, completed investigational studies, and evidence of disease-modifying activity	Evaluated

*CIRM will utilize various pre-submission components as follows:

- Eligibility: Will be used for internal confirmation that the project meets CIRM eligibility requirements
- Evaluated: Will be used for pre-submission evaluations to determine responsiveness to the program, including program preferences
- Informational: Will be used for internal informational use

Pre-submission Instructions

CIRM Preclinical Development Program (PDEV)

Thank you for your interest in CIRM's preclinical development funding opportunity. The table below provides an overview of the PDEV program, the PDEV 2026 timeline, key information sources, and contact information.

AWARD OVERVIEW	
Award Objective	To accelerate completion of preclinical development, FDA IND clearance, and clinical trial startup for stem cell-based and genetic therapies.
Scope of PDEV Award	CIRM will support activities in the Pre-IND stage and/or the IND-enabling stage. CIRM will not accept applications under this program that propose timelines that exceed limits described below. Early PDEV (Pre-IND): $5,500,000; duration 30 months (inclusive of maximum optional 6 months for candidate optimization) Late PDEV (IND-Enabling): $7,500,000; duration 30 months (inclusive of maximum optional 6 months for trial startup activity following IND clearance)
Preferences	Review the PDEV PA for preferences relevant to this funding cycle.

SCHEDULES AND DEADLINES Subject to change with notice	
Pre-submission Due	Pre-submissions must be fully submitted by 2:00pm (PDT/PST) on Thursday, June 12, 2025
Application Due Date	Approximately 60 days post pre-submission deadline
Grants Working Group (GWG) Review	Approximately 60 days post application submission deadline
Award Approval	Approximately 120 days post application submission deadline
Start Date	Must be ready to start award activities within 90 days of award approval
CONTACT AND ADDITIONAL RESOURCES	
PDEV Program Announcement <link> CIRM Funding Opportunities: Common Requirements and Definitions <link> For additional information on the program, pre-submission, or applications, contact preclinical@cirm.ca.gov. <link> For questions related to the review and approval of applications, contact review@cirm.ca.gov. <link>	

PDEV Pre-submissions

This is a **pre-submission form** to be used by CIRM to identify the most responsive preliminary proposals to be invited to submit a full PDEV application in the upcoming award cycle.

You must read the PDEV Program Announcement (PA) <link> and CIRM Funding Opportunities: Common Requirements and Definitions <link> carefully to understand the eligibility criteria, scope, budget limits, allowable activities, and all other requirements for this funding opportunity before proceeding. The PA also describes CIRM's selection and award administration processes for PDEV. PDEV awards are subject to the Grants Administration Policy <link>, the Intellectual Property and Revenue Sharing Requirements <link>, and additional regulations that can be found in our Grant Regulations. <link>

Please download and populate the current PDEV pre-submission template from the Document Uploads section of this form. Templates from a different CIRM program or prior PDEV review are not appropriate.

Eligibility

PDEV projects must fully satisfy several eligibility requirements that are described in the PDEV PA <link> and CIRM Funding Opportunities: Common Requirements and Definitions <link>. These include a requirement that the PI be from California-based (CA-based) organization. CIRM has a specific definition of a CA-based organization as follows:

> *A "California Organization" is a for-profit or non-profit organization or is a California-domiciled wholly owned subsidiary of a non-California organization (any entity that does not qualify as a California Organization) that meets all of the following criteria:*
>
> *1. Employment and Payroll:*
>
> *a. Employs at least one W-2 employee; and*
>
> *b. More than 50% of its W-2 employees, whether part-time or full-time, who are paid in any manner (e.g., wage, salary, commission, equity), must be domiciled*

full-time in California and be required to file California state income taxes due to their employment with the organization.

2. Management of Award Activities: The Principal Investigator (PI) must be physically located in California while overseeing all project activities.

3. Intellectual Property Rights: In the case of a California-domiciled wholly owned subsidiary of a non-California organization, the subsidiary must retain exclusive rights to any intellectual property arising out of the CIRM-funded project as well as any pre-existing IP rights held by the parent organization.

Eligibility Certification

[ ] <required certification> I, the PI, certify that I have read and understood the eligibility criteria in the PDEV PA <link> and CIRM General Eligibility Requirements and Applicant Resources <link> and to the best of my knowledge will be able to meet these criteria in the full application (if invited).

Complete and Accurate

[ ] <required certification> I acknowledge that in order to submit the pre-submission all required components of the pre-submission must be complete and may not contain any false or inaccurate information.

Personnel

Section	Instructions	Format
PI	The PI is the individual, designated by the Grantee, responsible for the scientific or technical aspects of the CIRM-funded Project or Activity and for its management.	Name: Title: Institution: Department: Address: Phone: Email: Role on Project: Percent Effort: Role Description: (450 characters)
Key Personnel	Key Personnel are defined as (1) the principal investigator or program director; or (2) any other person, including an independent consultant or an employee of a Subcontractor or Partner, who is expected to contribute to the scientific development or execution of the project in a substantive, measurable way and who is expected to: (a) receive or has been promised income, or anything else of value, of $10,000 or more per year for his or her contribution to the project or (b) contribute one percent (1%) or more effort to the proposed project. "Key Personnel" does not include a person who is	List here all key personnel as defined above: Name: Title: Institution: Department: Address: Phone: Email: Role on Project: Percent Effort: Role Description: (450 characters)

	expected to be involved in the proposed project but who does not satisfy conditions (1) or (2). Individuals who do not meet the definition of key personnel should not be identified here.	

Project Information

Section	Instructions	Format	Utilization
Project Title	Provide a brief title for your proposed project.	Text entry (120 characters)	Informational
CIRM Funding Requested for Development Stages	For which stages of development is the applicant requesting CIRM funding?	Check all that apply: [ ] Candidate optimization [ ] Pre-IND stage [ ] IND-enabling stage [ ] Trial startup	Informational, Eligibility
Therapeutic Candidate	What is the therapeutic candidate that will be studied under this project?	Text box (150 characters)	Informational, Eligibility
Proposed Mechanism of Action	What is the (proposed) mechanism of action of your therapeutic candidate?	Text box (150 characters)	Eligibility. Evaluated
Indication	What is the target indication for the therapeutic candidate?	Text box (150 characters)	Eligibility, Evaluated
Disease burden in CA	Provide California disease burden information for the proposed indication per 100,000. Helpful resources include CA Community Burden of Disease and Cost Engine (https://skylab.cdph.ca.gov/communityBurden/), CDC WONDER (https://wonder.cdc.gov/), and CAL*Explorer (cancer only; https://explorer.ccrcal.org/).	California Prevalence: (integer) California Annual Incidence: (integer)	Evaluated
Value proposition	Describe the value proposition of the proposed therapy for patients and the healthcare system.	Free text (1000 characters)	Evaluated, Informational
Disease treatment landscape	Describe the current standard of care for the target indication and indicate any approved disease modifying therapies.	Free text (1000 characters)	Evaluated
Major activities	Highlight key planned activities.	Text box (1000 characters)	Eligibility
INTERACT meeting	Has an FDA INTERACT meeting been conducted for the proposed therapy in the proposed indication?	Check one: [ ] Yes [ ] No	Evaluated

		Date of meeting:	
Pre-IND meeting	Has an FDA Pre-IND meeting been conducted for the proposed therapy in the proposed indication?	Check one: [ ] Yes [ ] No Date of meeting:	Evaluated
Portfolio pipeline	Was the development of the proposed therapy in the proposed indication supported by a prior CIRM award? i.e., DISC2 or TRAN	Check one: [ ] Yes [ ] No Previous CIRM Award Details:	Evaluated
Therapeutic approach	Select the most relevant category for your therapeutic candidate.	Checkbox, required, can select only one [ ] Allogeneic cell therapy [ ] Allogeneic gene-modified cell therapy [ ] Autologous cell therapy [ ] Autologous gene-modified cell therapy [ ] Biologic, excluding gene therapy [ ] Genetic therapy (cell-free) [ ] Small molecule	Evaluated
Therapy Description	Select the most relevant description for your therapeutic candidate.	As applicable, please specify the following: **Cell source** [ ] Adult hematopoietic stem cell [ ] Adult immune cell [ ] Adult mesenchymal stem cell [ ] Embryonic stem cell [ ] Induced pluripotent stem cell [ ] Other adult stem cell [ ] Other cell type **Gene delivery** [ ] Non-viral delivery [ ] Viral delivery [ ] Viral and non-viral delivery [ ] To be determined	

		[ ] Other **Vector type** [ ] AAV [ ] Adenovirus [ ] Lentivirus [ ] Episomal [ ] Retrovirus [ ] Other Virus [ ] Other **Editing method** [ ] CRISPR [ ] Prime/Base [ ] TALEN [ ] To be determined [ ] Other	
Disease Areas	Select at least one disease or tissue area that would most likely be impacted by a successful outcome of the proposed project, or select 'other'. If not applicable, select N/A.	**Checkbox, required, single selection only** [ ] Bone & Cartilage Disorders [ ] Brain Cancers [ ] Cancers, Multiple Types/sites [ ] Cardiovascular Disorders [ ] Eye/Vision Disorders, Neurological [ ] Eye/Vision Disorders, Non-neurological [ ] Hematological Malignancies [ ] Hematology Disorders [ ] Infection/Infectious Disease [ ] Metabolic Disorders [ ] Muscle Disorders [ ] Neurological Disorders [ ] Respiratory Disorders [ ] Skin Disorders [ ] Solid Tumors [ ] Other [ ] N/A	Evaluated

Neurological Disease Area	If you selected "Neurological Disorder" above, select the most relevant type of neurological disorder	[ ] Neurodegenerative Disorders [ ] Neuroinjuries [ ] Neurodevelopmental Disorders [ ] Neuropsychiatric Disorders [ ] Other Neurological Disorders	Evaluated

Document Upload: Candidate Eligibility and Disease Modifying Activity

The PDEV pre-submission requires a single document upload with the following sections. You will not be able to submit until the upload is complete. Information provided in this upload will be used to determine the eligibility of your project for CIRM funding. The upload can include tables and figures.

Section	Instructions	Format
Candidate Eligibility	Provide scientific evidence to demonstrate that the proposed therapeutic candidate meets one of the eligible candidate types as described in the PDEV Program Announcement (PA) <pages> <link>.	Up to two pages
Summary of Investigational Studies	Using the template below, provide a tabular summary of relevant, completed investigational studies conducted with the candidate or an analog/surrogate. For PDEV eligibility, at least one entry must be a completed study demonstrating reproducible disease modifying activity of the candidate in an in vitro or in vivo preclinical model that is relevant to the target indication. This eligibility requirement is described in the PDEV Program Announcement (PA) <pages> <link>. Column 1 (Study Objective): Enter a brief study identifier or title, e.g., 'Safety #1,' 'Safety #2', 'Efficacy #1',' Efficacy #2,' 'Distribution #1,' 'PKPD #1,' 'Immunogenicity #1,' the approximate date of the study, and the objective(s) of the study. Column 2 (Study Design): Specify the following: • The test article, using 'Therapeutic Candidate,' 'Surrogate Candidate,' 'Mouse Therapeutic Analog,' etc., plus identifiers such as named cell line(s). For example, if your proposed 'therapeutic candidate' were WA-07-derived cardiomyocytes, mouse ESC-derived cardiomyocytes would represent a 'mouse therapeutic analog.' WA-07-derived NSC expressing a GFP reporter would be a 'surrogate candidate.' • Whether research grade or cGMP compatible production methods were used for preparation of the test article. • The type of test and/or model used, the study arms, e.g., doses and controls (if applicable), and time points for data collection. • Sample sizes (i.e., number of animals, samples, biological replicates per time point, per arm), and the total n for the study. Column 3 (Key Outcomes): Summarize key study outcomes. Include statistical tests used, effect sizes, and levels of statistical significance, where appropriate. Provide accession number or other identifier if the study has been published.	Three column table

Disease Modifying Activity	Explain how your proposed product has achieved readiness for the PDEV program as described in the PDEV Program Announcement (PA) <pages> <link>: Reproducible, disease-modifying activity must be demonstrated with the candidate in preclinical model(s) relevant to the target clinical indication(s). First, outline the available assays, methods, tests, or models for measuring the therapeutic characteristics of your product. Indicate which of these you have used in the studies above, why, and reference the identifiers from column 1. If testing is limited by availability of models, explain how. Second, explain how the results of the studies in the above table demonstrate readiness for the PDEV program in terms of reproducible, disease-modifying activity with the candidate in preclinical model(s) relevant to the target clinical indication(s).	Up to one page