CIRM
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

Allowable Project Costs and Co-Funding

FREQUENTLY ASKED QUESTIONS (FAQ)

The purpose of this document is to provide applicant and awardee guidance regarding CIRM's allowable project costs and co-funding. Specifically: 1) Allowable project costs related to the location of the organization and when costs can begin to be incurred; 2) Co-funding requirement and warrant-based co-funding option. For the entire Allowable Project Costs policy please refer to CIRM's Grants Administration Policy for Clinical Stage Projects or Grants Administration Policy for Discovery, Translation, & Education Projects. For any additional questions about co-funding, please contact legal@cirm.ca.gov.

Allowable Project Costs

Key Definitions:

Incurred: CIRM considers the definition "incurred" based on U.S. Generally Accepted Accounting Principles ("GAAP") accrual basis of accounting. GAAP generally states that a liability, as well as its underlying expense, has been "incurred" when a present obligation exists that requires an entity to provide economic benefits to others enforceable by courts or from governmental actions that have the force of law. An exception to this definition is a prepaid asset as described below.

Prepayments (prepaid assets): CIRM considers the definition of "prepaid asset" based on GAAP. A prepaid asset is the deferral of costs/expense resulting from a current cash payment that have yet to be realized.

a. Prepayments are required to be deferred and capitalized, even when there is no alternative future use for the research and development.
b. See Scenario 10 below for an example of allowable prepayment costs.

California Organization: A "California Organization" is a for-profit or non-profit organization or 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:

a. Employment and Payroll:
    i. Employs at least one W-2 employee; and
    ii. 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.

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

Non-California Organization: A Non-California Organization is any organization that does not qualify as a California Organization.

Allowable Costs: Allowable Costs are those costs permitted under CIRM policies and regulations and include direct, facilities, and indirect costs. CIRM will not fund costs that exceed the specified Award amount.

Allowable Project Costs for research funded by CIRM are detailed in the CIRM Grants Administration Policy for Discovery, Translation, and Education Projects and the CIRM Grants Administration Policy for Clinical Stage Projects. Generally, project costs for personnel, supplies, travel, equipment, data sharing/management and subcontracts may be claimed. Limits for specific cost categories must be observed.

a. CLIN2 Projects: For a California Organization, Allowable Project Costs include:
    i. The per subject share of the costs of clinical and non- or pre-clinical research activities that are directly attributable to the treatment of patients enrolled in the proposed clinical trial; and
    ii. Costs of manufacturing activities for a subsequent clinical trial, contingent on 1) an interim evaluation by CIRM and a panel of independent experts of the clinical trial data to date, and 2) provision of 50% co-funding for this activity, if co-funding is required for the overall award.
b. CLIN2 Projects: For a Non-California Organization, Allowable Project Costs include:
    i. The per subject share of the costs of clinical and non- or pre-clinical research activities, whether conducted in California or outside of California that are directly attributable to the treatment of California patients enrolled in the proposed clinical trial; and
    ii. The costs of manufacturing conducted in California for the proposed clinical trial for patients enrolled, provided such costs are deducted before calculating the per subject share of costs; and
    iii. Costs of manufacturing conducted in California for a subsequent clinical trial contingent on 1) an interim evaluation by CIRM and a panel of independent experts of the clinical trial data to date, and 2) provision of 50% co-funding for this activity, if co-funding is required for the overall award.

Unallowable Costs:

a. Costs incurred on or prior to ICOC approval are not allowable, regardless of the status of the organization as a California organization.
b. Allowable Project Costs do NOT include the costs of activities performed by a separate out-of-state organization that retains intellectual property or independent publication rights in any intellectual property (e.g., invention, technology, data) arising out of the CIRM funded project.
c. For a non-California CLIN2 applicant, the per subject share of the costs of clinical and non-clinical research activities, whether conducted in California or outside of California, that are not directly attributable to the treatment of California subjects enrolled in the proposed clinical trial.

Non-CA Organization FAQs:

1. **Are Non-California Organizations eligible to apply to CIRM?**

   CIRM was created to benefit California researchers and organizations therefore Non-California Organizations may only apply to the CLIN2: Clinical Trial Stage Projects and EDUC1: Funding Opportunity for Conference Grants due to the nature of the projects and related activities.

2. **We are a Non-California Organization at the time of our Clinical application but will become a California Organization prior to contracting. What should we do?**

   For Clinical Stage programs, CIRM determines whether an applicant organization is "California-based" immediately after application submission, then again if the application is approved before executing an award contract, and finally at each Operational Milestone achievement point.

   If a Non-California Organization CLIN2 applicant believes that it will become a California Organization by the time it would need to execute an award contract, then the Non-California Organization may budget for allowable project costs available to California Organizations. If the entity is not California Organization by the time the contract is executed, CIRM will reduce the budget before executing the award contract. Similarly, if a California Organization becomes a Non-California Organization after a Clinical award is executed, CIRM will reduce the award amount effective at the time of the entity's change in status. Finally, if a Non-California Organization becomes a California Organization after Board approval and its budget did not include allowable costs for a California Organization, CIRM cannot increase funding for the project.

3. **Can a wholly owned subsidiary of a Non-California Organization qualify as a California Organization if it meets the requirements?**

   A California-domiciled wholly owned subsidiary of a non-California organization can qualify as a California Organization if it meets the requirements of a California Organization with respect to Employment and Payroll; Management of Award Activities; and Intellectual Property Rights as set forth above.

4. **If a Non-California Organization ("NCO") plans to conduct a clinical trial and applies for a CLIN2 award to conduct a part of the trial at a site or sites in California, what are the allowable project costs?**

   The allowable project costs include the per subject share of all costs for allowable project activities directly attributable to the treatment of California patients incurred after the date the ICOC approves the application for funding. For example, if the NCO intends to enroll 100 patients in a clinical trial, 20 of whom will be treated at a site located in California, it must first determine the total per subject costs for the clinical trial (including chemistry, manufacturing and controls ("CMC")/manufacturing, CRO services, etc.) and then multiply the per patient costs by the number of patients expected to be treated in California. Thus, if the per patient costs are $100,000, $2.0 million of the trial expenses would be considered allowable project costs.

5. **If a Non-California Organization ("NCO") plans to conduct a clinical trial and applies for a CLIN2 award to conduct a part of the trial at a site or sites in California and contracts with a California CRO to assist with the clinical trial, what costs are considered allowable costs?**

   The NCO may use CIRM funds to pay the per patient share of all allowable clinical trial costs directly attributable to the treatment of California patients. The only exception to per patient cost rule is for manufacturing. If an NCO conducts its manufacturing for the clinical trial in California, it may treat the full costs of manufacturing in California incurred after the date the ICOC approves the application for funding as an allowable cost, provided that it deducts the manufacturing costs before it calculates the per patient share of costs.

6. **If a Non-California Organization plans to conduct non- research in California, what costs are considered allowable costs?**

   The NCO may use CIRM funds to pay for the costs of the project activities conducted wholly in California incurred after the date the ICOC approves the application for funding.

7. **If a parent company has patents and exclusively grants the rights to a CIRM-funded indication to the wholly owned California-domiciled subsidiary but keeps rights to other indications in the parent company, would that be acceptable to CIRM?**

   Depending upon the contract terms (such as termination rights), the answer will probably be yes.

Allowable Project Cost FAQs:

8. **Can required co-funding be used towards unallowable costs?**

   No. CIRM considers Allowable Project Costs to be those costs covered by CIRM funding as well as the applicant's co-funding (when required). Applicants should first determine what qualifies as Allowable Project Costs and then apply the co-funding percentage to determine the minimum amount of co-funding required.

9. **When are allowable project costs considered to be incurred under CIRM policy?**

   Allowable project costs are costs that are incurred after ICOC-approval. CIRM considers the definition "incurred" based on U.S. Generally Accepted Accounting Principles ("GAAP") accrual basis of accounting. GAAP generally states that a liability, as well as its underlying expense, has been "incurred" when a present obligation exists that requires an entity to provide economic benefits to others enforceable by courts or from governmental actions that have the force of law. This means that allowable project costs are generally considered to be incurred when the related services have been rendered by a supplier or vendor, but the awardee has not yet been invoiced for the respective efforts. This differs from the cash basis of accounting (not GAAP) whereby expenses are considered incurred when the entity has paid for the expense.

10. **Given I have an active, ongoing project at the time I apply for CIRM funding, when can I "start the clock" for budgeting and start incurring allowable project costs that can be recovered by the CIRM-funded project?**

    For an ongoing project, you may only include costs incurred after the estimated date of the CIRM Board's approval of your application. Check the Program Announcements for when you can estimate receiving Board approval. For Clinical Stage applications, approval can happen in as early as 3 months after application submission though it may take longer due to resubmissions which could require rebudgeting before CIRM executes a contract. If you have costs for manufacturing or other contracts that you pre-paid before the date of CIRM Board approval and is allocable to the CIRM-funded

project, you may include the portion of those pre-paid costs that will be incurred for the CIRM-funded project.

11. **Are manufacturing costs incurred to produce completed drug product that are then used to treat patients in active clinical trial(s) considered an allowable pre-paid cost?**

    No. In accordance with GAAP, manufacturing costs for products that have not received regulatory approval (i.e. FDA approval) will generally be expensed when incurred which is typically upon their manufacture or upon the receipt from the respective contract manufacturing organization ("CMO"). Therefore, these are not considered allowable cost under CIRM policy if they are incurred before ICOC approval. However, these manufacturing costs could qualify as an allowable cost if services rendered by CMO are incurred after ICOC approval.

12. **If an applicant applies for funding to support an on-going clinical trial, are the costs incurred to treat patients enrolled prior to the date of ICOC approval of the application considered allowable project costs?**

    No, the costs of treating patients enrolled prior to the date of ICOC approval of the application is only allowable if those costs are incurred after the ICOC application approval date.

13. **If Allowable Project Costs for services to perform research and development are rendered by a Contract Research Organization or CMO prior to ICOC approval, but there is a delay in billing such that invoices were received after ICOC approval would this qualify as an allowable cost?**

    No. Expense for these services are considered to be incurred when the related services provided by these vendors has occurred, not when the invoice for the services is received and / or the services have been paid. Furthermore, given the expenses were incurred prior to ICOC approval they are not allowable under CIRM policy.

<u>Clinical Stage Allowable Cost Scenarios:</u>

14. **If an applicant applies for a CIRM award to support an on-going clinical trial and the ICOC application approval date occurs on June 30, 2025, are manufacturing costs incurred with a contract manufacturing organization ("CMO") to support clinical trial on or before June 30, 2025, allowable costs?**

    No, as CMO costs were (a) incurred prior to first patient dosing to support the active clinical, and (b) prior to ICOC approval, they are not allowable costs. Even if the drug

manufactured was used to treat patients after ICOC approval on June 30, 2025, this would not be allowable cost because manufacturing costs were incurred when applicant is legally obligated to pay manufacturer for services performed to manufacture the drug product and/or therapeutic. However, costs incurred to treat patients at clinical sites incurred by CRO or awardee managing the site after June 30, 2025, are allowable costs and should be accurately tracked after June 30, 2025.

15. **An applicant submits for a CIRM award to support a near-term clinical trial. ICOC approval occurs on June 30, 2025. Upon initiation of contract on January 1, 2025, the applicant made a 50% advanced payment to CMO for manufacturing activities yet to be completed. On September 1, 2025, the applicant receives notice that the CMO has commenced activities and on September 30, 2025, the manufacturing activities are completed. Are manufacturing activities performed in September 2025 an allowable cost?**

    Yes, although the payment for these manufacturing activities was made in January 2025 upon execution of CMO contract, the costs were not incurred until completion of the related services in September 2025 which was after ICOC approval on June 30, 2025. As such, these manufacturing costs are an allowable cost.

16. **Applicant submits for a CIRM award to support a near-term clinical trial on April 30, 2025. Due to application re-submission the applicant does not receive ICOC approval until November 30, 2025. Applicant knowing ICOC approval will not occur until several months contacts CMO to delay billing until 2025. Manufacturing services commenced in August 2025 and were completed in October 2025. Are manufacturing activities performed in August and September 2025 an allowable cost?**

    No, as CMO costs were incurred between August 2025 and October 2025, which is prior to ICOC approval on November 30, 2025, they are not allowable costs. Even if the invoice for the drug product and/or therapeutic manufactured was not received until 2025 which is after ICOC approval they would not be allowable cost because manufacturing costs were incurred when applicant is legally obligated to pay manufacturer for services performed to manufacture the drug. The only costs allowable would be those that were incurred after the ICOC approval date of November 30, 2025.

Other FAQs and Scenarios:

17. **A California Organization plans to apply for funding for research, including work performed by an out-of-state collaborator under the California principal investigators ("PI's") direction and control. The California Organization will retain**

all IP rights. Can the out-of-state collaborator be a co-author on a paper that arises from the work?

Yes, although work performed by an out-of-state collaborator may not be treated as an allowable cost if the out-of-state collaborator retains "independent publication rights," the term "independent publication rights" means the right to publish separately from the PI, as opposed to participating as a co-author on a publication along with the PI. Because the out-of-state collaborator would not retain independent publication rights or IP rights in the CIRM-funded research and would work under the California PI's direction and control, the work would be considered an allowable cost.

18. **A California organization plans to apply for CLIN2 award to conduct a clinical trial. The applicant plans to contract with NIH/TrialNet to collect and publish clinical trial data, including data collected from the treatment of out-of-state subjects. Is the cost of the TrialNet contract considered an allowable cost?**

    Yes, TrialNet is a clinical trial network comprising investigators who agree to collect and publish clinical trial data through TrialNet. As discussed above, because TrialNet does not retain independent rights to publish, but rather publishes with the consent of the sponsor and the PI, the cost of the contract will be considered an allowable cost, provided that the California PI exercises direction and control over TrialNet and TrialNet does not retain IP rights in the CIRM-funded research.

19. **The policy states costs for activities performed by a separate out-of-state organization that retains IP or independent publication rights arising out of the CIRM-funded project are not allowable. What does that mean?**

    CIRM funds cannot be used for "research" being conducted outside of California. To define what constitutes "research", our policy identifies the most common characteristics of what constitute a 3rd party subcontract for research activities: one in which the 3rd party retains IP or independent publications rights arising out of their portion of the CIRM-funded project. If a 3rd party retains such rights, their work would not be considered an allowable cost. If the 3rd party waives both its IP and independent publication rights, then CIRM can fund such work.

20. **Is this the totality of CIRM's policy on allowable costs?**

    No. In addition, interested parties should read CIRM's Allowable Project Costs Policy and p.31-34 of the Grants Administration Policy for Clinical Stage Projects for a list of allowable and unallowable direct project costs, facilities and indirect costs as well as pre-award and post-award allowable project costs.

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Co-Funding

CIRM Preclinical & Clinical Programs

Non-Profit Co-Funding Requirements

1. **How is the co-funding requirement applied for a non-profit applicant with a for-profit partner?**

   If, at the time of application submission, the non-profit applicant has a for-profit partner for the proposed project, the for-profit partner is required to commit the minimum co-funding amount for the project as described in the Preclinical and Clinical Program Announcements. The for-profit partner may elect to commit to the cash co-funding option, the warrant-based co-funding option or a combination of the two.

   If the non-profit applicant does not have a for-profit partner for the proposed project at the time of application submission, the minimum co-funding requirement does not apply.

2. **What constitutes a for-profit partner for the proposed project?**

   CIRM's Preclinical and Clinical Program Announcements define "Partner" as an organization that, in exchange for the right to the opportunity for a future financial return, has (1) agreed to provide matching funds for the proposed project or (2) entered into an agreement with the applicant organization relating to the commercialization of the proposed product.

   Examples of a for-profit partner of a non-profit applicant include, but are not limited to, entities that have entered into any type of agreement with the non-profit applicant, such as a license, option, or sponsored research agreement, that confers IP rights for commercialization of the proposed product.

3. **Are materials/reagents vendors, service providers, or subcontractors such as Contract Research Organizations, Contract Manufacturing Organizations considered for-profit partners of a non-profit application?**

   Vendors, service providers and subcontractors that do not meet the definition of "Partner" and are delivering a standard product or service for completion of project activities would generally not be considered for-profit partners of a non-profit applicant. Vendors, service providers and subcontractors that require a license for use of their proprietary technology in the proposed project are also unlikely to meet the definition of a for-profit partner unless they retain commercialization rights to the proposed product.

4. **If the proposed project involves development of a product for which the non-profit applicant has licensed intellectual property rights from a for-profit licensor, is the for-profit licensor required to commit minimum co-funding?**

   Generally, a for-profit licensor is unlikely to meet the definition of a for-profit partner of a non-profit applicant for purposes of the co-funding requirement unless the licensor retains commercialization rights to the proposed product or receives CIRM funding for proposed project activities.

5. **Whom do I contact if I need additional clarification on the co-funding requirements for non-profit applicants with a for-profit partner?**

   You may contact legal@cirm.ca.gov for additional questions and clarifications on the co-funding requirements for for-profit partners of non-profit applicants to CIRM's Preclinical and Clinical Programs.

Warrant-Based Co-Funding Requirement

1. **Are my only options to co-fund with cash or warrants?**

   No, you may elect to co-fund with cash-only, warrant-only, or a combination of cash and warrants.

2. **How do I determine if the warrant-based co-funding is a relevant option for my proposed Preclinical or Clinical project?**

   The warrant-based co-funding option allows an awardee (or its for-profit partner) to request CIRM funding up to the award limit in return for issuing warrants to CIRM for the amount of CIRM funding that represents a proportion of the minimum co-funding requirement. Since the awardee is not allowed to request CIRM funding above the award limit and since the co-funding is a percentage of total CIRM allowable project costs, the warrant-based co-funding option is viable for projects that have total allowable project costs ranging between the CIRM award limit and the sum of the CIRM award limit and minimum co-funding requirement.

   We advise applicants to start by completing the Activities Based Budget and then to complete the Solvency & Co-Funding Template.

3. **What are some scenarios demonstrating the utility of the warrant-based co-funding requirement?**

   Below are illustrative examples of cash-based co-funding, warrant-based co-funding and combined cash and warrant-based co-funding for a CIRM-funded project.

Proposed Project: CLIN2 applicant with a phase 2 clinical trial.
Applicant: For-Profit
CLIN2 Award Limit: $15M
CLIN2 Co-Funding Requirement: 50% of total allowable project costs

Example 1: Total Allowable Project Cost = $12M

CIRM Award: $6M (50% of total project costs)
Awardee Cash Co-Funding: $6M (50% of total project costs).

If the applicant elects the warrant-based co-funding option:
CIRM Award: $12M
Awardee Cash Co-Funding: $0
Amount of CIRM Funding Attributed to warrant-based co-funding: $6M

Example 2: Total Allowable Project Cost = $15M

CIRM Award: $7.5M (50% of total project costs)
Awardee Cash Co-Funding: $7.5M (50% of total project costs).

If the applicant elects the warrant-based co-funding option:
CIRM Award: $15M
Awardee Cash Co-Funding: $0
Amount of CIRM Funding Attributed to warrant-based co-funding: $7.5M

Example 3: Total Allowable Project Cost = $20M

CIRM Award: $10M (50% of total project costs)
Awardee Cash Co-Funding: $10M (50% of total project costs)

If the applicant elects the warrant-based co-funding option:
CIRM Award: $15M
Awardee Cash Co-Funding: $5M
Amount of CIRM Funding Attributed to warrant-based co-funding: $5M

Example 4: Total Allowable Project Cost = $30M

CIRM Award: $15M (50% of total project costs)
Awardee Cash Co-Funding: $15M (50% of total project costs)

The warrant-based co-funding option is not applicable.

4. **How is equity amount determined in warrant-based co-funding?**

   The number of warrant shares is based on the most recent valuation of the company. Please see warrant term sheet for reference.

5. **Where can I find the terms for the warrant issuance to CIRM?**

   The document uploads section of applicable Preclinical and Clinical Applications has the warrant term sheet template. Alternatively, you may email legal@cirm.ca.gov for a copy of the warrant term sheet.

6. **How do I elect the warrant-based co-funding option in the CIRM grant application?**

   A Preclinical or Clinical Program applicant must indicate that they elect the warrant-based co-funding option at time of application submission. The applicant is also required to attach a signed Warrant Term Sheet as a document upload in the submitted application.

   To generate a signed Warrant Term Sheet: After reviewing the warrant term sheet template and after determining that warrant-based co-funding is a viable option for the proposed project, please contact legal@cirm.ca.gov to initiate a DocuSign version of the Warrant Term Sheet for inclusion in the CIRM Preclinical or Clinical Grant Application. Provide the name and email of the signing official for the applicant organization (or for-profit partner of the non-profit organization).

7. **Is the Warrant Term Sheet negotiable?**

   No.

8. **If the application is approved for funding, is the warrant negotiable?**

If the grant application is approved for funding, CIRM and the awardee may negotiate on a limited basis prior to drafting of the form of warrant and issuance of warrants to CIRM.

9. **If I had elected the warrant-based co-funding option at time of application submission, can I convert to cash-based co-funding during the award contracting period if my application is approved for funding?**

   Yes, an awardee may elect to convert to the cash-based co-funding requirement during the award contracting period. The CIRM award amount will be correspondingly reduced and the awardee must demonstrate committed co-funding for the project.

10. **Does electing warrant-based co-funding have any impact on the application review?**

    No, all applications are reviewed by the Grants Working Group based on the criteria defined in the Program Announcement.

11. **When must warrants be issued?**

    Warrants must be issued at award start.

12. **Is it possible to buy back the warrants after the award start?**

    No. It should also be noted that any modifications or terminations to the contracted CIRM award will have no impact on warrants issued to CIRM.

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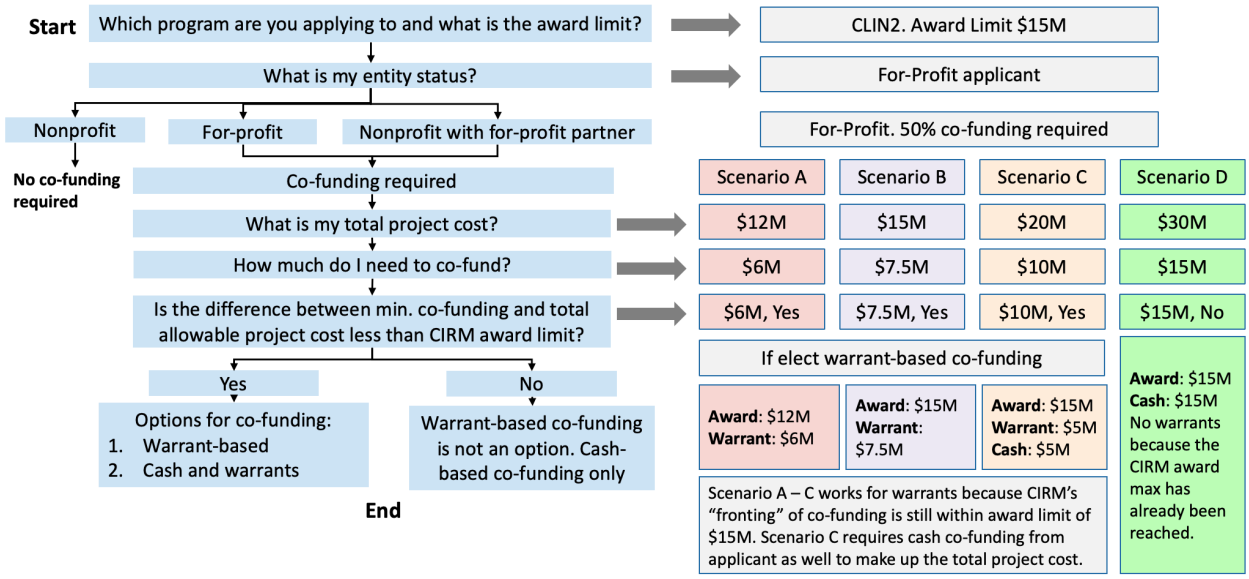
Appendix A: Warrant Co-Funding Decision Guide



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