

Patient Support Program Update

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ICOC/ARS Meeting
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Goal for Today

To provide an update on the status of the CIRM Patient Support Program (PSP), what we've learned to date, and to answer any questions about the program

Patient Support Program Update

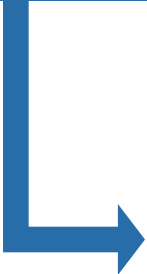
- 1 Background
- 2 Timeline
- 3 Program Pilot and Improvement Areas
- 4 Next Steps

Proposition 14 - Patient Assistance Fund (PAF)

*Revenues received by CIRM shall be deposited into the General Fund “Licensing and Revenue Fund” to be spent on “offsetting the costs of providing treatments and cures arising from Institute-funded research to **California** patients who have insufficient means to purchase such treatment or cure, including the reimbursement of patient-qualified costs for research participants.” - Proposition 14 125290.30(j)(1)*

Strategic Allocation Framework (SAF)

Goal 5 - Ensure that every BLA ready program has a strategy for access and affordability



Strengthen Clinical Infrastructure Connectivity

- Build interconnectivity & performance metrics between CIRM Clinical Infrastructure (Alpha Clinics, CCCEs, PSP) to ensure enhanced **referral, enrollment, & retention** of California patients in clinical trials

Program Funding - Grant vs. PAF

Funds to directly cover patient costs

- Dedicated to allowable expenses for eligible CA residents in CIRM funded trials
- Fund may be supplemented by future CIRM royalty streams

Patient Assistance
Fund (PAF)
15.6M

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Patient Assistance
Fund (PAF)
15.6M

Patient
Support
Program
(PSP)
2.5M

CIRM INFR7 Award

- Grant for program design planning, and operational expenses
- Supported by CIRM AA budget
- Issued to ensure that the PAF is utilized to directly address patient financial and logistical barriers

Patient Support Program (PSP) Award

- The PSP awardee was required to perform **4 primary operational activities**:
 1. **Patient intake and navigation** through development of a call center
 2. Assessing **patient financial eligibility** for access to PSP support
 3. **Distributing payments for eligible expenses** for transportation, travel, lodging, and nutrition
 4. Coordinating with CIRM and trial sites to **maintain accounting and assurance of non-duplication of permitted costs**

PSP Support Services Offered



Nutrition

Meals or other nutritional assistance (up to \$100/day for patient, \$50/day for caregiver)



Travel

Travel coordination (e.g. flight booking up to \$500 per flight for patient & caregiver)



Lodging

Lodging throughout clinical visits (\$275 per night)

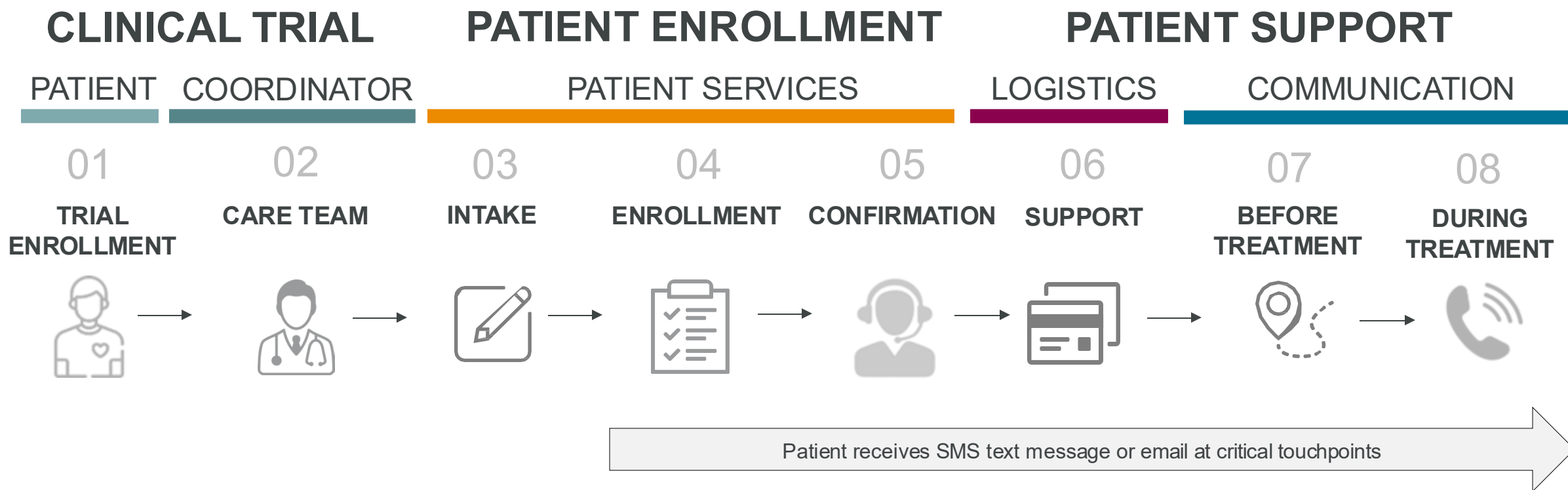


Transportation

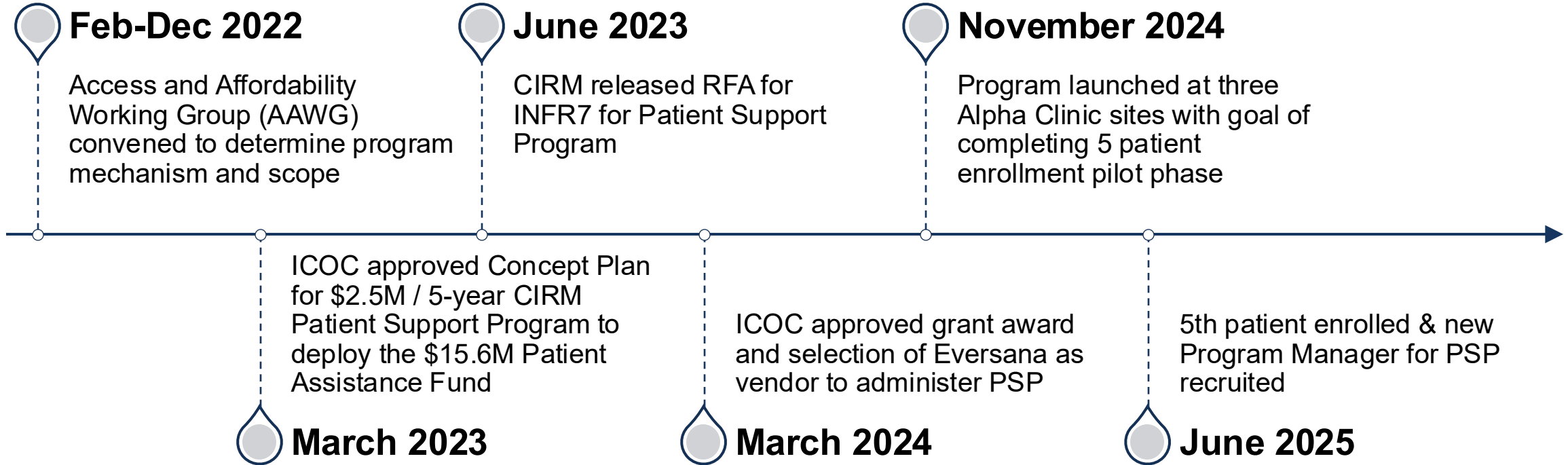
Including gas, ride share and parking (\$50 limit)

Program exceptions for additional funds are reviewed on a case-by-case basis, consistent with State travel policy

PSP Patient Journey



PSP Development Timeline



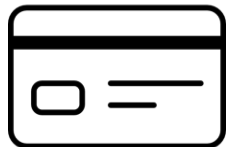
PSP Initial Pilot



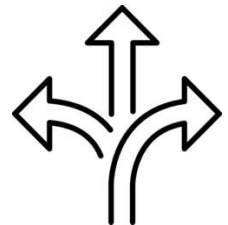
Program well received by participating clinical trial sites, Alpha Clinics, and patients



Smooth enrollment process through text and email allows for efficient communication with patients



Use of pre-paid debit card increases accessibility and reduces administrative burden on patients



Program infrastructure adaptable to emerging needs (e.g. ground transportation, additional service offerings)

PSP Pilot Improvement Areas



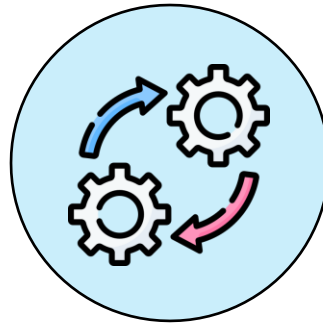
Reporting

Modifying reports to be **more robust** for comprehensive expense category reporting



Compliance

Refining allowable merchant codes and transaction tracking



CLIN2 Outreach

Increasing awareness with CLIN2 study teams and Alpha Clinics



Policy & Legal

Engaging CIRM Legal and Finance to inform program **eligibility and compliance** questions



Navigation

Implementing **enhanced clinical navigation** support

PSP Pilot Extension

Q3 24-25	Q4 24-25	Q1 25-26	Q2 25-26
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PSP Initial Pilot

- Operational framework, call center scripting, platform and business rules developed
- Debit card vendor (Klyre) and travel vendor (Concur) contracted
- Program launched at 3 Alpha Clinics 12/24
- Fiscal agreement finalized 1/25
- Program expanded to all Alpha Clinics and CLIN2 award sites 5/25
- Program expanded to support screening 6/25
- Fifth patient enrolled 6/25

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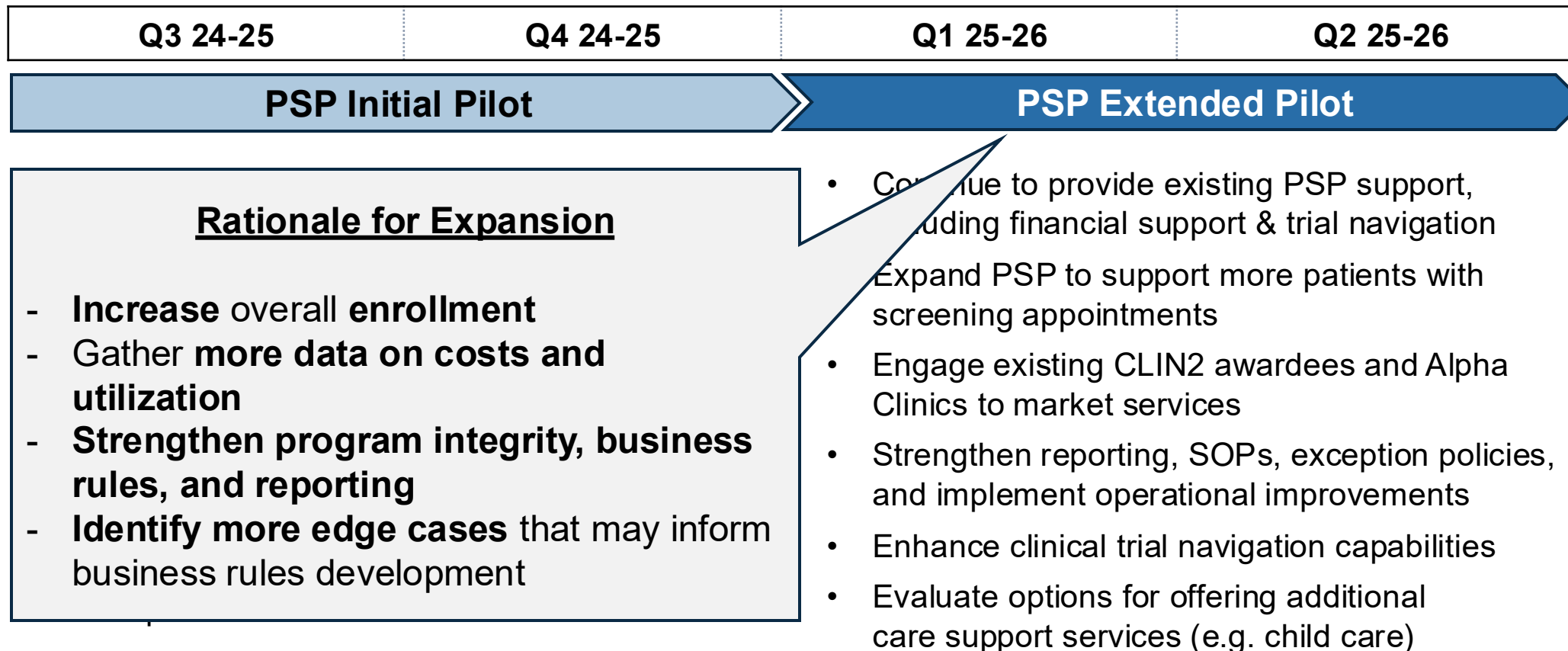
Limitations of Pilot

- **Low overall patient volume**
- **Only 3 clinical trial sites**
- **Not enough data** on costs and utilization
- **Not enough variety** of data on patient usage to identify edge cases to **strengthen business rules**

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PSP Initial Pilot		PSP Extended Pilot	
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PSP Pilot Extension



PSP Award Implementation Schedule

Award Start: 8/1/2024
Award End: 7/31/2029



Phase 2
Discovery
1/1/26 – 6/30/26

- Move into full program implementation as more CLIN2s come online



Phase 3
Expansion
7/1/26 – 12/31/26

- Solidify full program implementation



Year 3
Steady State
1/1/27-12/31/27

- Steady state program implementation



Year 4
Steady State
1/1/28-12/31/28

- Steady state program implementation



Year 5
Assessment
1/1/29-7/31/29

- Wind-down of award
- Ramp up next phase of program (if applicable)

Questions?