

Strategic Allocation Framework (SAF) Update

Rosa Canet-Avilés, Ph.D.
Vice President, Scientific Programs and Education
June 27, 2024



1 Background

2 SAF Mandate

3 SAF Process Update

4 Next Steps

1 Background

2 SAF Mandate

3 SAF Process Update

4 Next Steps



Advance World Class Science

- Develop shared resources
- Build knowledge networks



Deliver Real World Solutions

- Advance therapies to marketing approval
- Create a manufacturing partnership network
- Expand Alpha Clinics Network
- Create Community Care Centers of Excellence



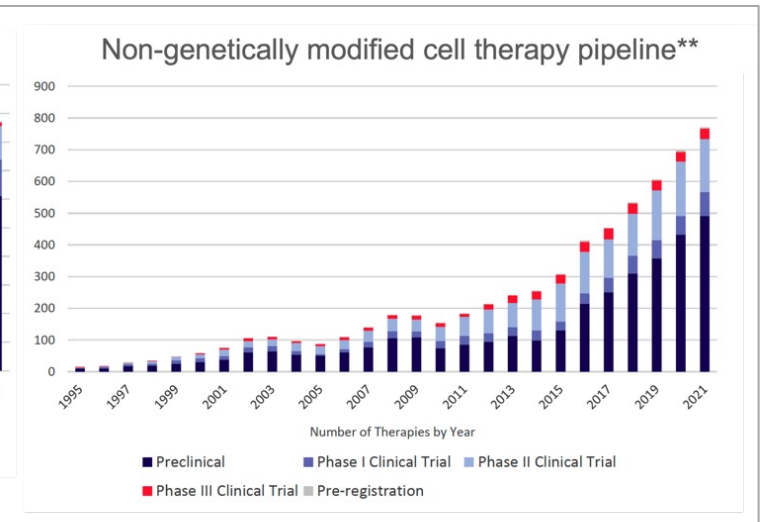
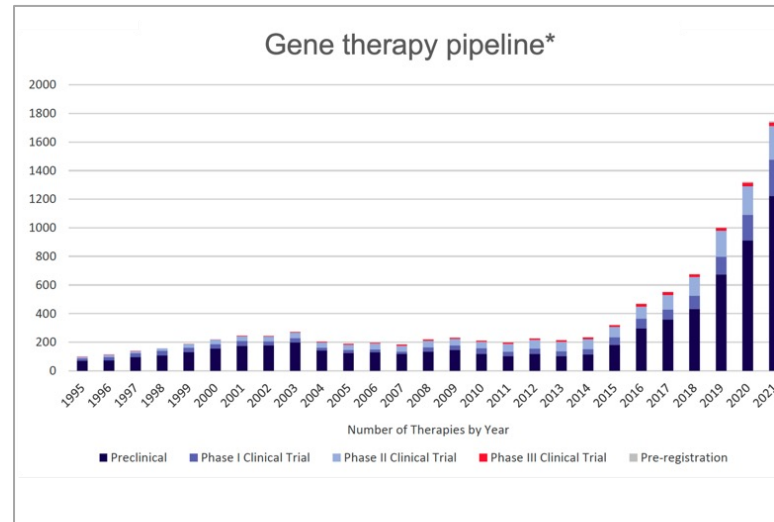
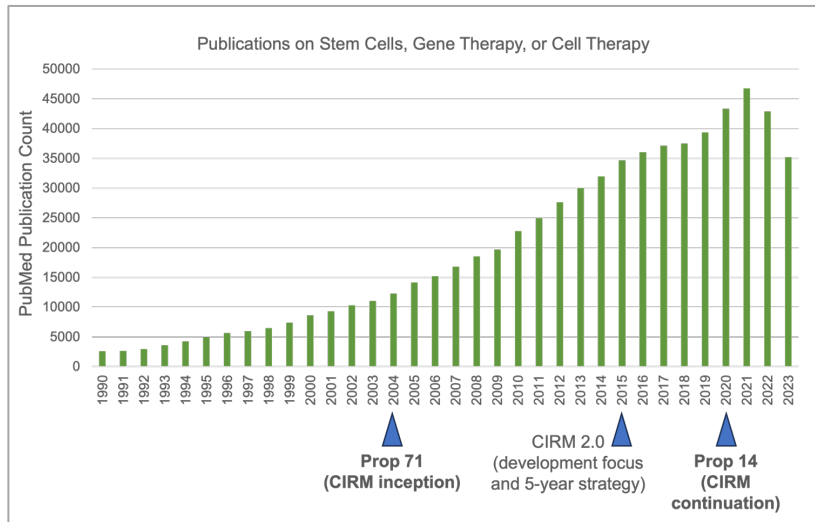
Provide Opportunity for All

- Build a diverse and highly skilled workforce
- Deliver a roadmap for access and affordability

CIRM must allocate remaining resources to maximize its impact by considering available funds and reviewing past strategies

- CIRM has established itself as a leader in stem cell and regenerative medicine, funding basic research, infrastructure, education/training, and regenerative medicine discovery and clinical development
- Since CIRM's inception, the regenerative medicine field has grown exponentially
- CIRM has finite resources
- Demand for CIRM funding exceeds available resources

Exponential growth in the number of stem cell and genetic therapies companies, products, academic faculty, research projects and clinical trials from 2005 to 2022



The regenerative medicine field is expanding rapidly, increasing the need for strategic allocation in funding

Total Research Budget

From Prop 71 & Prop 14

\$7.64B



Current Research Allocation

Excluding expended/scheduled payments & approved allocations

Remaining Balance: **\$3.86B**, of which:

- For Neuro Research: **\$1.14B**
- Access & Affordability: **\$94M**

1 Background

2 SAF Mandate

3 SAF Process Update

4 Next Steps

- September 2023 Science Subcommittee: Prioritization Kickoff Discussion (BM Fischer-Colbrie)
 - **Outcome:** Ask for CIRM staff to develop an approach and recommendations for prioritization
- March 2024 Science Subcommittee and ICOC: Presented SAF and continued process with September 2024 target for recommendations

The **Strategic Allocation Framework (SAF)** is a structured and data-driven approach to prioritize resource allocation and provide recommendations to the ICOC for continued implementation of CIRM's strategic plan

1 Background

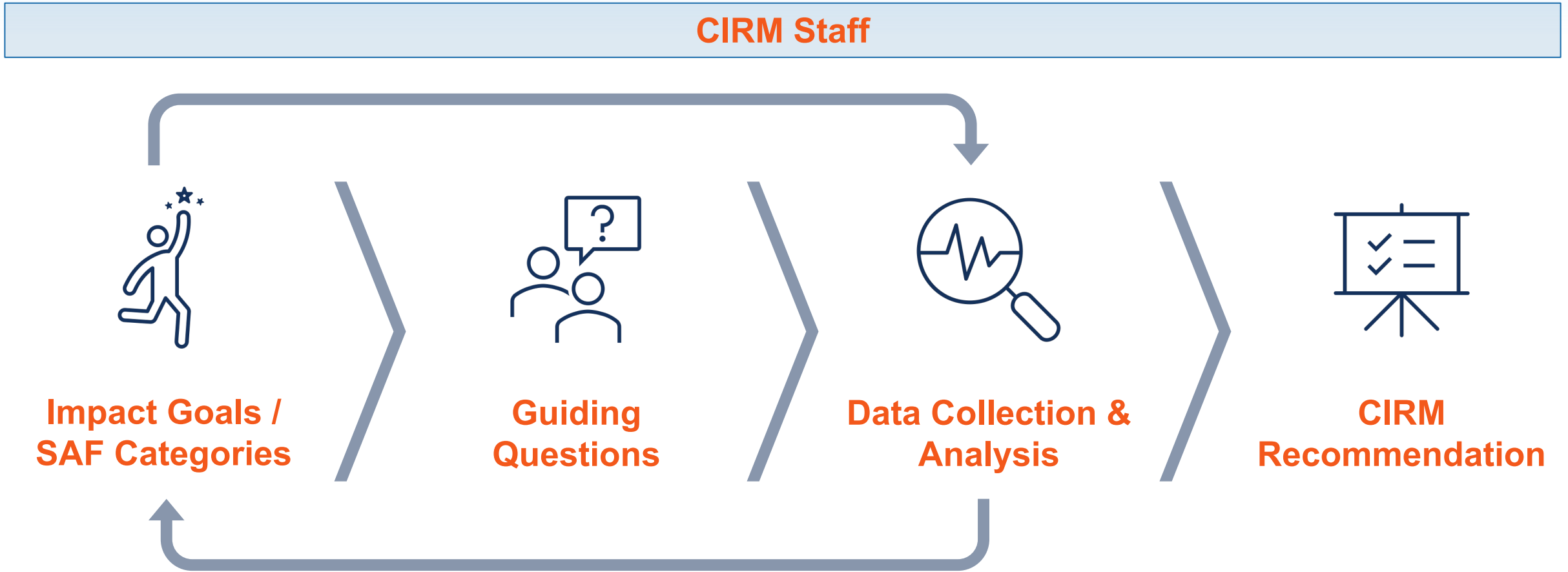
2 SAF Mandate

3 SAF Process Update

4 Next Steps

Determine:

- How can CIRM make the greatest impact on its mission?
- How might CIRM effectively allocate its remaining budget of \$3.86B?
 - How might CIRM effectively allocate its remaining **Neuro budget of \$1.14B?**



*Science Subcommittee, NTF, AAWG will inform specific aspects of the Recommendations

1. Accelerating Discovery & Translation
2. Cell & Gene Therapy Approvals
3. Accessibility & Affordability of CIRM-Funded Cell & Gene Therapies
4. Diverse Workforce Development

Accelerating Discovery & Translation

1. **Catalyze** the identification and validation of at least **X** novel targets and biomarkers, ensuring integration into preclinical or clinical research for diseases in California
2. **Accelerate** development and utilization of **X** technologies that demonstrate improvements in safety, efficacy, and quality of cell and gene therapies

Cell & Gene Therapy Approvals

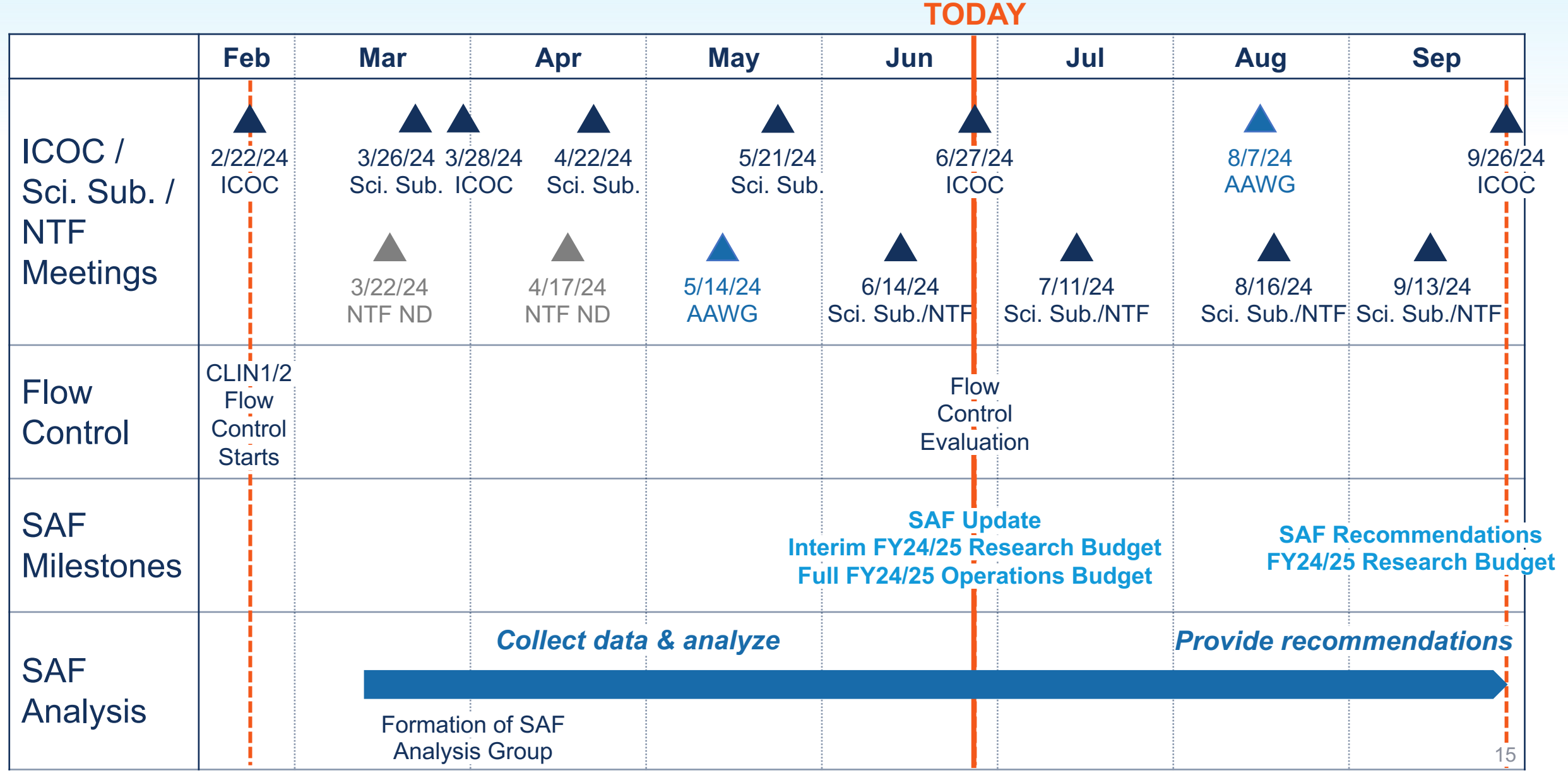
3. **Advance** at least **X** rare disease projects to BLA
4. **Propel** **X** therapies targeting distinct prevalent diseases in California to late-stage trials, including a neurological condition, to significantly reduce morbidity and mortality

Accessibility & Affordability of CIRM-Funded Cell & Gene Therapies

5. **Ensure** that every CIRM funded project completing a late-stage clinical trial has a strategy that enables access and affordability by all California patients, particularly underserved populations

Diverse Workforce Development

6. **Enhance** the integration and real-world application of training programs through strategic partnerships



	Sep	Oct	Nov	Dec
ICOC / Sci. Sub. / NTF Meetings	<p>▲ 9/26/24 ICOC</p> <p>▲ 9/13/24 Sci. Sub./NTF</p>		<p>▲ TBD AAWG</p> <p>▲ TBD Sci. Sub./NTF</p>	<p>▲ 12/12/24 ICOC</p> <p>▲ TBD Sci. Sub./NTF</p>
Flow Control				
SAF Milestones	SAF Recommendations FY24/25 Research Budget			
SAF Follow Up	<p><i>Develop & Amend Concepts</i></p>			

1 Background

2 SAF Mandate

3 SAF Process Update

4 Next Steps

Meeting	SAF Topics
June NTF/Science Subcommittee	<ul style="list-style-type: none"> • Strategic Analysis Framework (SAF) Overview – NTF Background • Present Neuro Survey Results – Discussion • Provide a high-level overview of how this fits within SAF
June ICOC	<ul style="list-style-type: none"> • Provide an update on the process, aligning with the June NTF/Science Subcommittee
July NTF/Science Subcommittee	<ul style="list-style-type: none"> • Present four overarching SAF Goals and delve into Goal 1 and 2 • Review relevant data associated with Goal 1 and 2 • Discuss potential recommendations for Goal 1 and 2
August NTF/Science Subcommittee	<ul style="list-style-type: none"> • Present updates based on feedback received on Goal 1 and 2 • Introduce Goal 3 & 4 and discuss associated data • Discuss potential recommendations for Goals 3 & 4
August AAWG	<ul style="list-style-type: none"> • Present updates on Goal 5 and discuss associated data • Discuss potential recommendations for Goal 5
September NTF/Science Subcommittee	<ul style="list-style-type: none"> • Full SAF presentation: <ul style="list-style-type: none"> • Present updates based on feedback received on Goals 1- 4 • Present Goal 5 (from AAWG feedback) and Goal 6 together, discussing strategies and data relevant to both
September ICOC	<ul style="list-style-type: none"> • Overall Presentation of SAF recommendations