Southern Star Research

BIOUTAH

AUSTRALIA: The Strategic Choice for Early-Phase Clinical Trials

INSIGHTS FOR USA & UTAH BASED BIOTECHS

PRESENTED IN PARTNERSHIP WITH BIOUTAH

THURSDAY 5TH JUNE 2025

Aim for today

1. Southern Star Research Introduction
2. Why Consider Australia?
3. Speed
4. Cost
5. Quality
6. IND v CTN Pathway
7. Case Studies
8. Unlocking R&D Tax Incentive
9. Q&A

WHO WE ARE

Australian Expertise, Global Capability

Southern Star Research is a full-service contract research organisation (CRO) dedicated to guiding sponsors through the complexities of bringing new medical products to market.

2010

Solid reputation built on trust and transparency

115

Permanent, in-house staff

CRO

An Australian powerhouse with a global reach

Client service

You won't get lost

Actively managing trials in Australia, New Zealand & East Asia. Also able to operate in Europe & the United States

WHO WE ARE

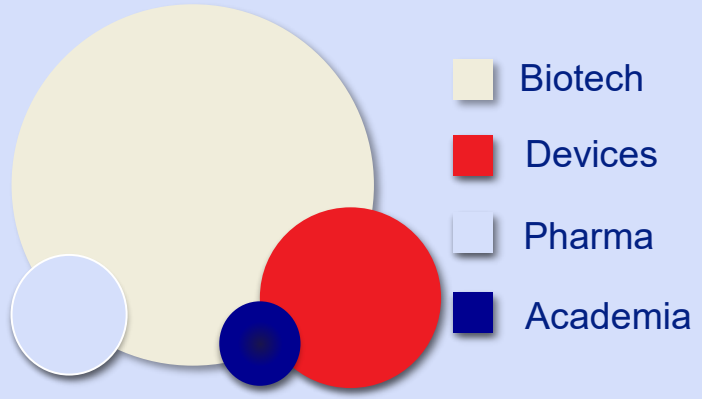
Southern Star Research: Our History

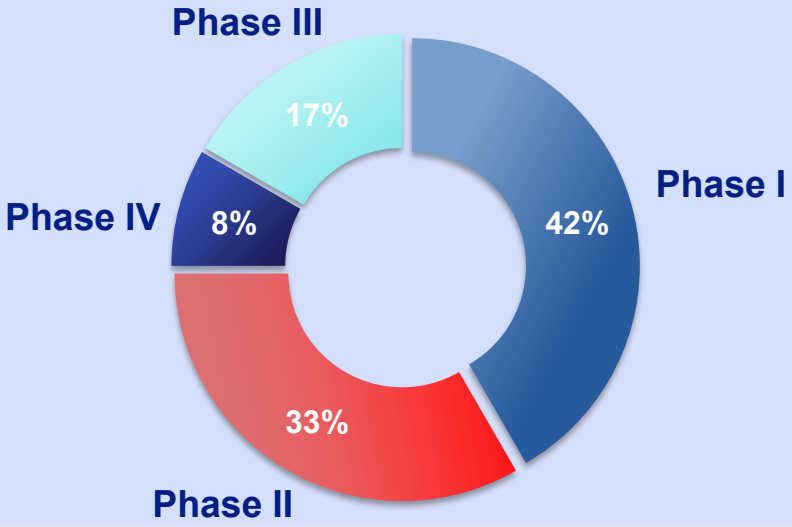
Founded in 2010

- Trusted by Australian Government
- Built on trust, transparency & quality
- Organic & Sustainable growth
- Focused on quality clinical trial delivery

Full-Service, End-to-End

- All services performed in-house
- No Outsourcing
- Large expert Biometrics & Data Management team located in Australia





RELEVANT EXPERTISE

Our Expertise in Phase I

100%

Of Operational Staff have Phase I Clinical Trial experience

120+

Completed Phase I Studies

- >45% of our trials are Phase I FIH
- SAD, SAD/MAD, PK, BA/BE, FE, DDI
- Dedicated Phase I Program Leads & Senior / PMs
- Deep Understanding of dynamic and fast-paced requirements for Phase I Programs
- Average of 16+ years experience across the Operational Team

WHO WE ARE

End-to-end clinical research services conducted to the highest standards

Clinical Operations

- Regulatory Affairs
- Study Start-Up
- Clinical Monitoring
- Project Management
- Vendor Management

Medical

- Medical Monitoring 24/7
- Safety / PV
- Reporting to Authorities

Biometrics

- Biostatistics
- Data Management
- Medical Writing

QUALITY ASSURANCE

Tailored services that are assessed and decided upon with you – only pay for what you need

Services are conducted in-house

We can identify and manage your required vendors and partners

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Why Australia ?

WHY AUSTRALIA?

Key Facts – Australian Clinical Research

World Class Reputation

World Class Infrastructure

70% Overseas sponsors

Global Success Stories

Ethnically Diverse

Fast Facts

Population: 27 Million

Largest City: Sydney

Global Ranking Phase I Trials: #3

Global Ranking Phase II Trials: #4

Largest Biotech / Pharma / Med Device Companies: -

- CSL
- Cochlear
- ResMed

WHY AUSTRALIA?

A globally respected, stable & beneficial nation for Clinical Trials

No IND Required

A highly streamlined regulatory process

Up To 43.5% R&D Cash Refund

Non-Dilutive Funding

FDA & EMA Accepted Data

High Quality Data

Lower Trial Costs vs U.S. or EU

Cost-Effective clinical trials

Achieve Trial Approvals in 4-8 weeks

Ethics/IRB & Regulatory

Exceptional Early Phase Infrastructure

Fit for early-stage Biotech

WHY AUSTRALIA?

The Australian Advantages

"On average in Australia, the first patient into a clinical trial is about three months, whereas in the US or the EU, it's six to nine months — it's efficient"

Head of APAC, Beigene

SPEED

- CTN Scheme
- National Site Contract
- No IND Requirement
- Low Documentation Burden
- Ethics / IRB Approval 4-8 weeks

COST-EFFICIENCY

- 43.5% R&D Refund Available
- Lower Clinical trial Costs
- Favourable Exchange Rate

QUALITY

- FDA & EMA Accepted Data
- World Class Research Infrastructure
- ICH-GCP

STABILITY

- Consistent Governmental Support for Clinical Trials
- Predictable, straightforward Regulatory process

PLATFORM FOR EARLY STAGE BIOTECHS TO SUCCEED

Case Study: Phase I SAD | MAD Trial

Specifications

Phase 1 FIH

SAD then MAD

Overlapping cohorts based on SRC approval

Oral tablets

Stakeholders

Safety Review Committee (SRC)

SRC met after each cohort, reviewed available safety data and approved next steps

Design

Single Ascending Dose (SAD)

- 5 cohorts of 7 normal healthy volunteers
- 2 sentinel participants followed by 5 rest of cohort (ROC)

Multiple Ascending Dose (MAD)

- 3 cohorts
- Commenced after SAD cohort 3

Sites

Nucleus Network, Brisbane site and The Alfred HREC

Rapid Start-up

Site drove HREC submission

Rapid EDC build by Southern Star enabled strict FPI milestone

Case Study: SAD – MAD Cohort

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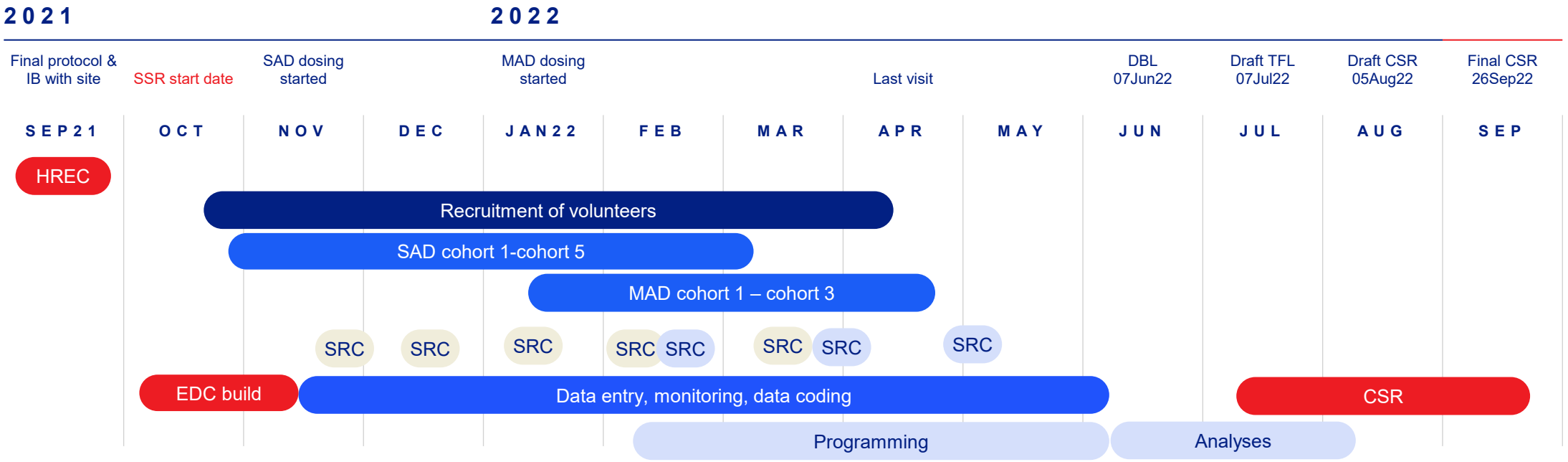

Summary

Study start-up
- HREC submitted 01Sep21
- HREC approved 23Sep21

Note - HREC was by site prior to SSR

- SIV 13Oct21
- EDC build 07Oct21 to 14Nov21 (27 business days)

Participant phase
- First consent 19Oct21
- SAD CH1 first dose 28Oct21
- SAD CH1 SRC 11Nov21

Safety Review Committee (SRC) Meetings
- One meeting per cohort
- Data monitored promptly by CRA
- Report of key safety data points & AEs sent to SRC members
- SRC meeting to review data and make decisions regarding next cohorts

Key Points

- Provided full-service support (excluding protocol writing), achieving fast site start-up through close collaboration with experienced site and rapid EDC build by Southern Star Research
- Collaborated closely with the site to manage the initial recruitment period without EDC, while seamlessly initiating MAD cohorts before completing the last SAD cohort
- Regular monitoring ensured timely delivery of data for the Safety Review Committee to make informed, data-driven decisions

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Australian R&D Tax Incentive

Unlocking the R&D Incentive

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Have an annual GROUP turnover / revenue of <$20m AUD

Be an Australian Incorporated Entity

Spend more than >$20,000 AUD on R&D Activities

Incur Tax Losses

Australian Entity Income	**$0**
Australian R&D Spend	$2,000,000
Australian Entity Profit/Loss	-$2,000,000
R&D Refund (43.5% x $2,000,000)	$870,000 Cash Refund
Losses Carried forward	N/A

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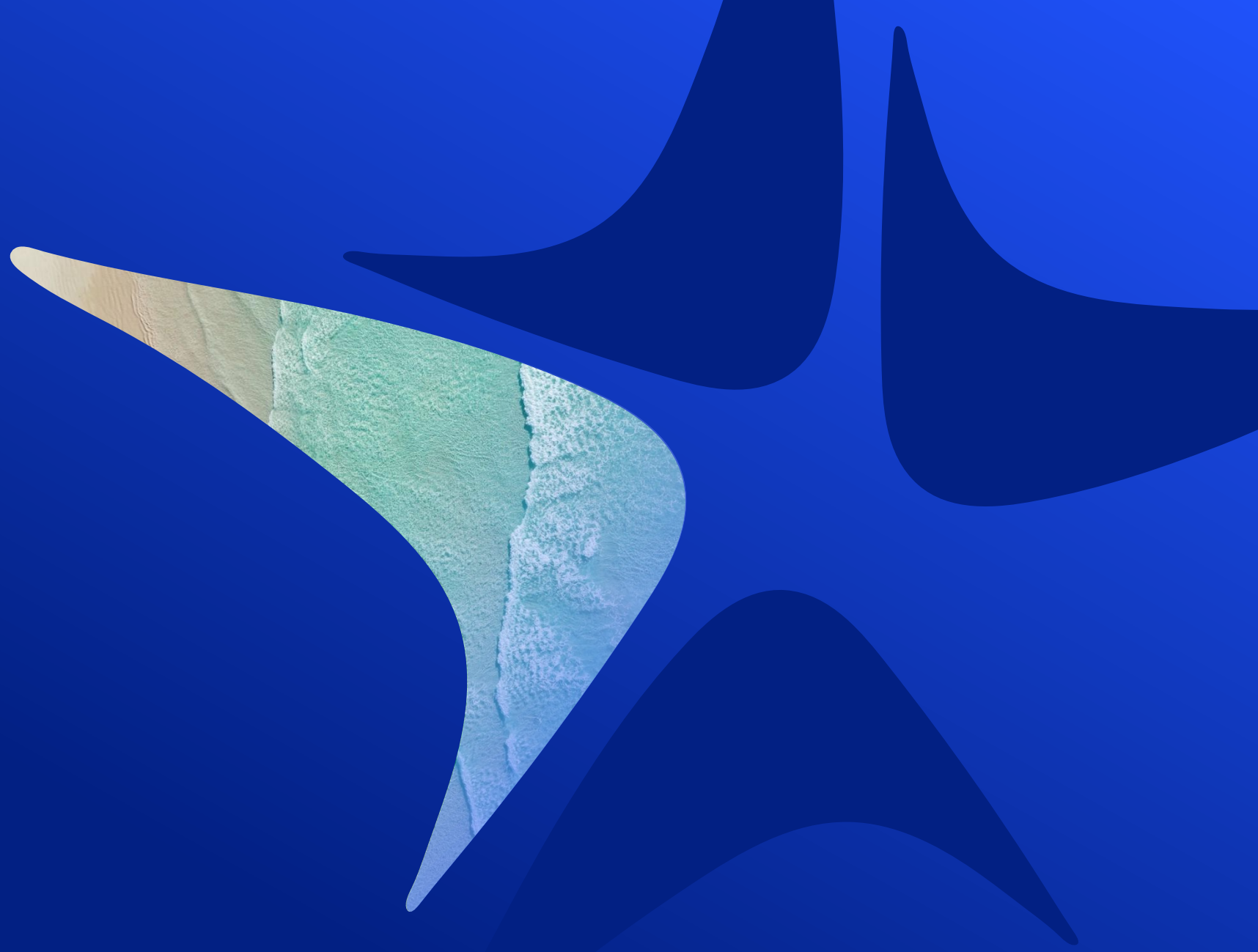

Q&A

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Thank You!

Daniel Evans
Director, Business Development
Southern Star Research
E: devans@southernstarresearch.com