

# ASX ANNOUNCEMENT



22 December 2025

## Second-tranche placement funding provides strong financial flexibility to advance Stabl-Im technology for the early and safe detection of brain tumours

### Highlights:

- **\$3.5m second-tranche placement funding received, strengthening TrivarX's balance sheet and providing flexibility to advance Stabl-Im into the clinic**
- **Funding to progress Stabl-Im preparatory activities, including manufacturing scale-up, quality-control validation and regulatory pre-submission work in the US and EU**
- **Stabl-Im targets early, safe and non-invasive detection of brain tumours, using stable isotope labelling and standard MRI without radiation or surgery**
- **First-in-human Phase 1 clinical trial planned for CY26, focused on safety, imaging precision and reproducibility in patients with confirmed brain tumours**

**Perth, Australia, and Minneapolis, USA: TrivarX Limited** ('the **Company**') (ASX: TRI) is pleased to advise it has received \$3.5m in new funding following settlement of the second tranche of the Company's strategic placement (refer ASX announcement: 16 October 2025). New funding provides TrivarX with balance sheet strength and exceptional financial flexibility to advance development of Stabl-Im.

Stabl-Im represents a potential breakthrough in the safe and non-invasive imaging of brain cancers and metastases. The platform utilises stable isotope labelling to identify replicating cells within the brain, which is a biological process that is absent in healthy adults but rapidly activated in the presence of a growing tumour. The platform detects cellular replication using standard Magnetic Resonance Imaging (MRI) equipment, providing a safe and non-invasive method to visualise and monitor tumour growth, without the need for radiation or surgical procedures.

New funding will be deployed towards targeted preparatory activities to advance the Stabl-Im platform into the clinic. This will include manufacturing scale-up and quality-control validation of the stable isotope compounds used in imaging, together with regulatory pre-submission activities across key jurisdictions, including the US and European Union.

These activities will be overseen by experienced regulatory and medical consultants, working alongside existing management, to support clinical pathway design and ensure alignment with applicable regulatory frameworks. The Company will also be supported by Dr Daniel Tillett, founder of Stabl-Im, who has agreed to provide ongoing technical input and advice across preclinical and clinical study activities.

A first-in-human Phase 1 clinical trial is expected to commence in CY26, with the objective of assessing safety, imaging precision and reproducibility of the Stabl-Im platform in patients with confirmed brain tumours. Interim study results and preliminary safety data are expected to inform progression toward broader, multi-site clinical trials.

A presentation providing further background on the technology and clinical development pathway is attached to this announcement.

**This announcement is authorised for release by the Board of Directors of TrivarX Limited.**

**ENDS**

## ASX ANNOUNCEMENT



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### About TrivarX Limited:

TrivarX (ASX: TRI) (OTCPINK: MDBIF) is a mental health technology company pioneering the use of objective measures to aid in the early detection and screening of mental health conditions. The Company was founded in Australia, with offices located in Perth (WA) and Minneapolis (MN, USA). TrivarX is listed on the Australian Securities Exchange Ltd and trades on the OTCQB Venture Market. Investors can find additional information on [www.otcmarkets.com](http://www.otcmarkets.com) and [www.asx.com.au](http://www.asx.com.au)

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The logo for TrivarX, featuring the word 'Tri' in blue, 'var' in purple, and 'X' in grey, all in a sans-serif font. The logo is contained within a white rounded rectangle with a blue border.

TrivarX

# STABL-IM™ - A POTENTIAL BREAKTHROUGH IN THE SAFE AND NON-INVASIVE IMAGING OF CANCERS

Investor Presentation – December 2025

ASX: TRI

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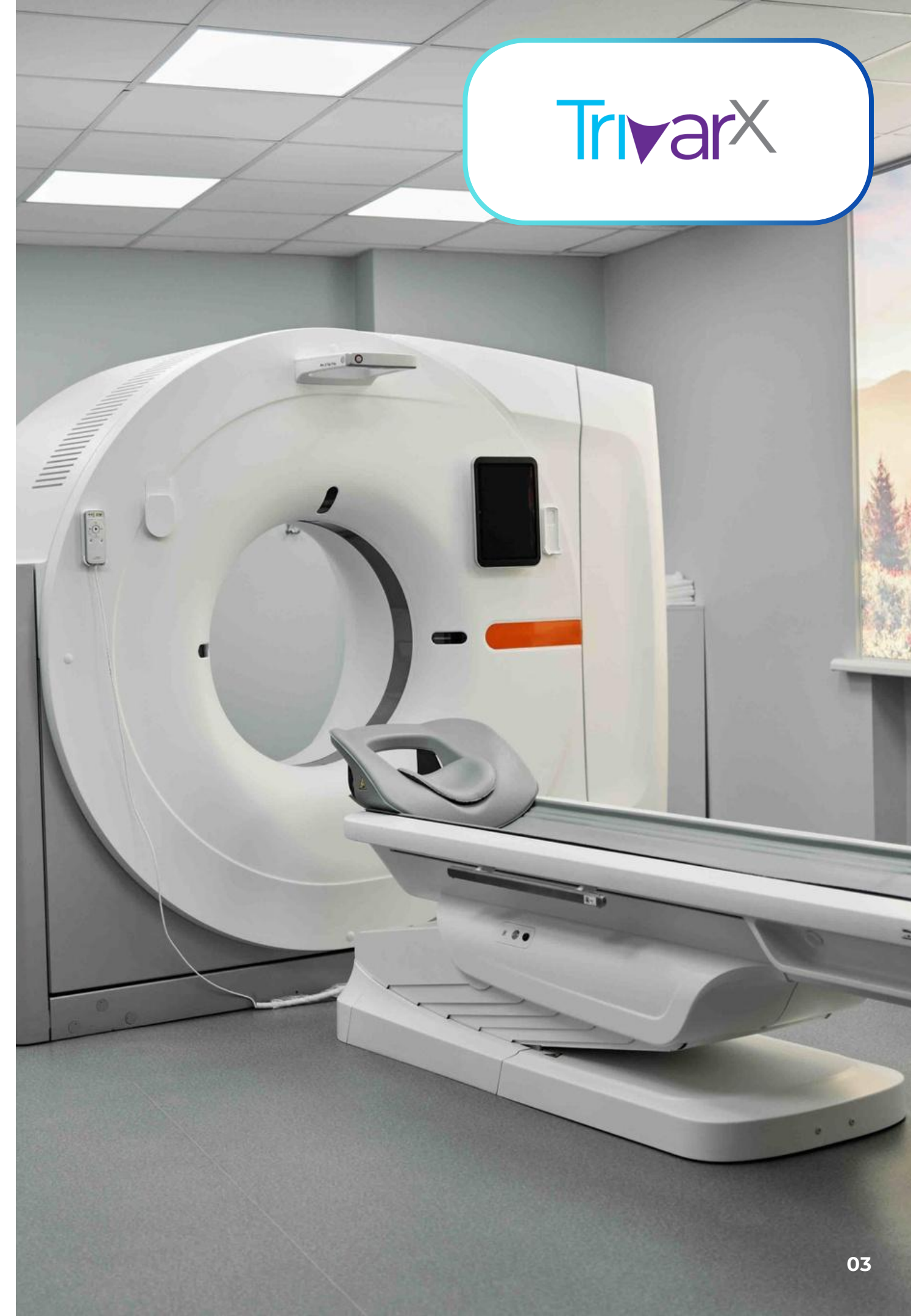
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# Stabl-Im™: A potential breakthrough in the safe and non-invasive imaging of brain and other cancers

- ▶ Acquired in December 2025 from Nucleics Pty Ltd
- ▶ Technology has potential to enable safe imaging and monitoring of brain cancers through standard MRI
- ▶ Stabl-Im™ uses stable isotope labelling of replicating cells within the brain for earlier detection of brain tumours
- ▶ Technology invented by Dr Daniel Tillett, a prominent biotech investor, industry leader and the CEO & Managing Director of Racura Oncology (formerly Race Oncology) Limited (ASX: RAC)
- ▶ Defined pathway to market with immediate works program to include manufacturing and quality control, FDA engagement and Phase 1 clinical trial early CY26

**Stabl-Im™ has the potential to address the limitations of the current standard of care**



# An opportunity to disrupt major markets

Innovative technology to pursue significant opportunities in the diagnostic imaging and neuro-oncological markets

## MARKET OVERVIEW

- Global diagnostic imaging market ~US\$600bn+**, with MRI a high-value, fast-growing segment
- Global MRI market ~US\$10–12bn**, growing ~**6–7% CAGR**, underpinned by oncology and neurology
- >40 million MRI scans annually**, creating strong leverage for innovations using the existing installed base
- MRI is the gold standard in neuro-oncology**, yet limited in distinguishing active tumour from treatment effects
- ~180,000 brain metastasis cases annually in the US**, with rising incidence and high unmet diagnostic need
- Stabl-Im™ addresses this gap** by enabling functional, non-radioactive tumour imaging on standard MRI systems



## KEY DRIVERS

- Increasing cancer survival rates**
- Better diagnostic imaging capabilities**
- Growing aging population**
- Lung and breast cancer prevalence**

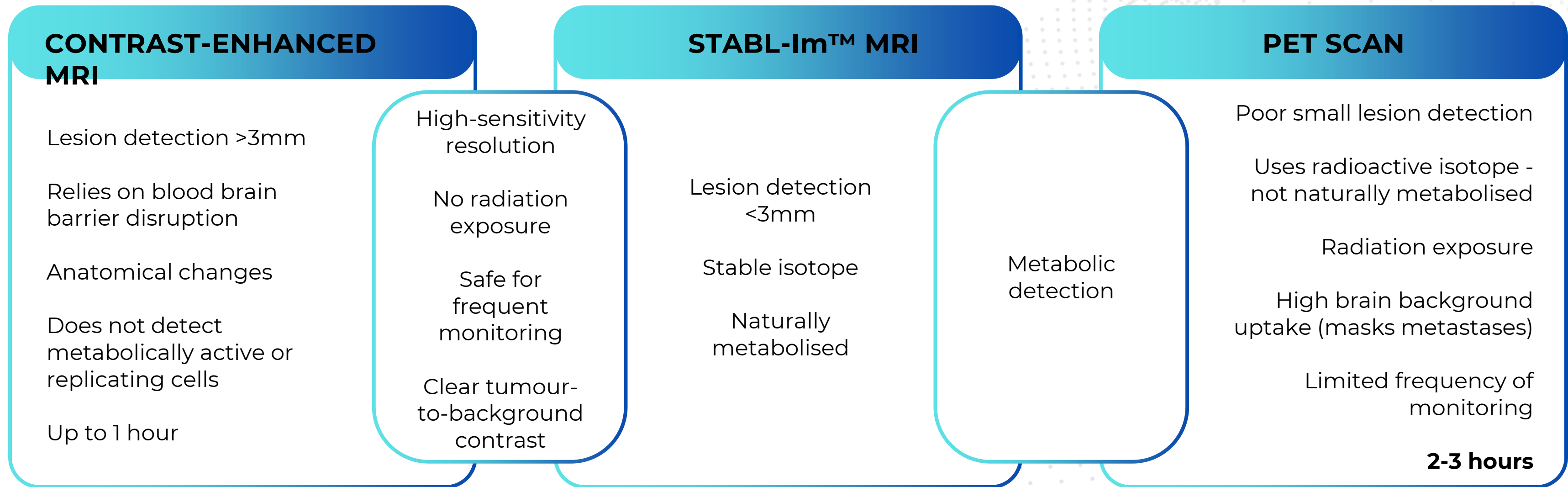
Critical unmet need: Despite advances in treatment, survival rates remain poor following brain metastases diagnosis, with most patients having short life expectancy. Early, safe and accurate detection is essential

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# Current standard of care

- Contrast-enhanced MRI is the gold standard for brain metastases detection and monitoring
- A PET (positron emission tomography) scan is used as an adjunct, particularly to differentiate progression from treatment effect

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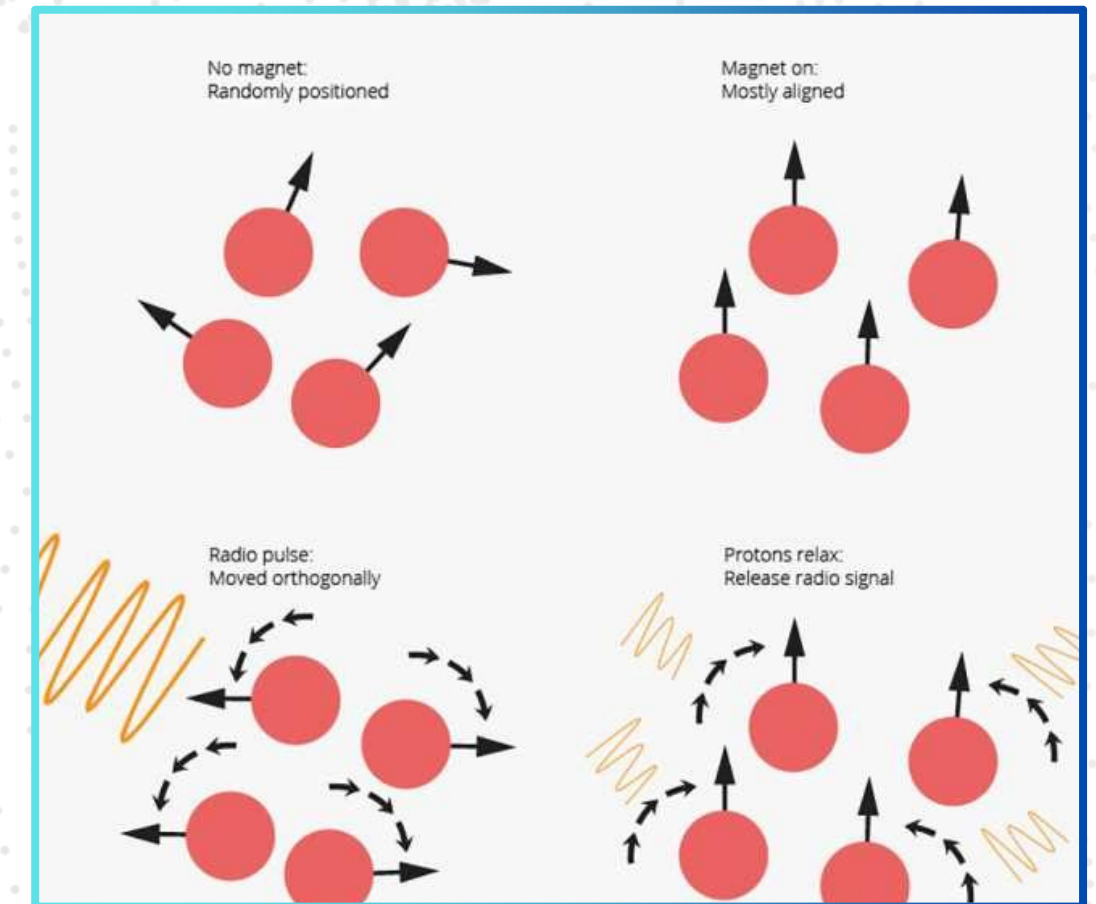
**Stabl-Im™ has the potential to combine the metabolic detection capabilities of PET with the safety, resolution and infrastructure advantages of MRIs to provide early response assessment and monitor progression frequently.**

# Magnetic Resonance Imaging (MRI) overview

MRI is an imaging technique that uses high magnetic fields and radio waves to visualize soft tissue – It has many applications but inherent limitations in detecting some diseases

## THE MRI PROCESS

- ▶ A strong magnet lines up hydrogen in the body
- ▶ Radio waves briefly knock this alignment out of place
- ▶ As the hydrogen settles back, it sends signals to the scanner
- ▶ Different tissues send different signals (e.g. water vs fat)
- ▶ This allows MRI to tell tissues apart
- ▶ But MRI mainly shows structure, not cell activity



**Stabl-Im™ is incorporated into dividing cells:**

Non-dividing cells (e.g. brain)



Dividing cells (e.g. cancer)



MRI signal



MRI signal

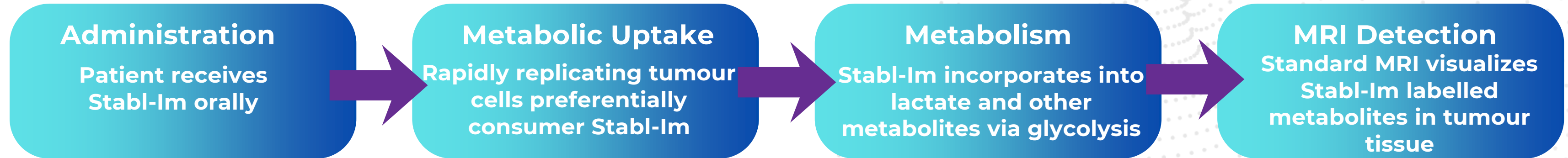


# Introducing Stabl-Im™ – Stable Isotope MRI

**Innovative technology that offers a potential breakthrough in the safe and non-invasive imaging of brain cancers**

Stabl-Im™ uses stable isotope labelling to identify rapidly dividing cancer cells in the brain through standard MRI equipment – offering a radiation-free, non-invasive diagnostic approach

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## KEY ADVANTAGES

- ▶ No radiation exposure
- ▶ Uses existing MRI equipment
- ▶ Detects metabolically active tumours
- ▶ Can monitor treatment response
- ▶ Repeatable for longitudinal tracking

## TECHNICAL FEATURES

- ▶ MRI is a non-radioactive imaging technique
- ▶ Identifies replicating cells specifically
- ▶ Differentiates tumours from normal tissue

# Safety in Humans

**Previously studies highlight that Stabl-Im™ is safe in animals, as well as humans, providing a strong foundation for planned Phase 1 clinical trial**

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- ▶ Stabl-Im™ is known to be safe in animals at up to 20% with no health impacts, even when consumed across multiple generations
- ▶ Limited study in humans, however, initial human research has shown no effects at up to 3%
- ▶ The highest human dose is currently unknown
- ▶ Determining the safest human Stabl-Im™ dose will provide further IP, which will be protectable by patent

## SAFETY ASPECTS

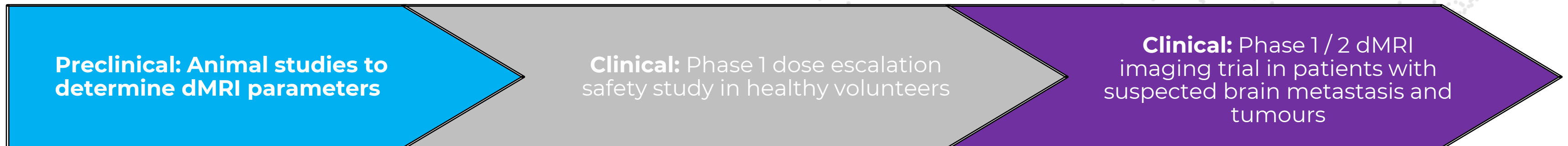
- ▶ No radiation (unlike PET scans)
- ▶ No cumulative radiation exposure
- ▶ Safe for repeated imaging sessions
- ▶ No special handling requirements
- ▶ Suitable for a broader patient populations

# Clinical and regulatory pathway

**Defined phase 1 regulatory pathway and near term works program provides a compelling value proposition underpinned by the potential to materially improve clinical outcomes**

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- ▶ **Clear Phase 1 regulatory pathway:** Stabl-Im™ is a stable, non-radioactive isotope classified as a food, supporting a streamlined early-stage regulatory approach
- ▶ **High-unmet orphan indication:** Brain metastases affect ~180,000 patients annually in the US, carry a very poor prognosis, and have limited, highly invasive treatment options
- ▶ **Strong orphan designation potential:** Orphan Drug Designation offers 7 years post-approval exclusivity, applicable to diagnostics as well as therapeutics
- ▶ **Stepwise clinical program includes:** Preclinical animal studies to optimise dMRI parameters, Phase 1 dose-escalation safety study in healthy volunteers, Phase 1/2 dMRI imaging trial in patients with suspected brain metastases and tumours
- ▶ **Efficient trial execution:** Patient population is typically excluded from trials, allowing simpler recruitment and faster progression



# Stabl-Im™ presents major advantages

Technology, potential efficiency of clinical trials and shorter-term regulatory pathway provides a considerable potential upside

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1

Non-radioactive MRI-based detection of rapidly growing cells (i.e. cancer) has the potential to considerably impact clinical decision making, unlock earlier intervention and improve quality of life

2

\$4.2m funding secured for development with Phase 1 planned in H12026

3

No chemistry, manufacturing, control (CMC) requirements – unlocking massive cost savings

4

Stabl-Im™ is known to be safe at low levels – IP (patent) obtainable from identifying the upper safety limits in humans via pending Phase 1 trial

5

Can be delivered anywhere in the body – no issues with the blood brain barrier or fibrotic tumours – highly important for brain and other cancers

6

Patients can be screened as often as desired without the use of radiation or contrast agents. Can potentially be used to determine the activity of cancer treatments more regularly unlocking multiple commercial opportunities

# Multiple near term value drivers

Defined works programs underpin potential for significant near term value creation

Activity	Timing
Key appointments to strengthen management team	January 2026
Completion of pre-clinical trial design requirements	January 2026
Commencement and completion of pre-clinical trial using Stabl-Im in animal studies	Q1 CY2026
Completion of Phase 1 clinical trial design and requirements	Q1 CY2026
Ethics approval for Phase 1 dose escalation study in healthy human volunteers	Q2 CY2026
Commencement of patient recruitment for Phase 1 study	Q3 CY2026
Undertake Phase 1 study in healthy human volunteers	Q3 CY2026
Completion of Phase 1 study	Q3 CY2026
Advance regulatory engagement initiatives with the US Food & Drug Administration	Q4 CY2026

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