
RESONANCE HEALTH CONTRACTED FOR TWO NEW CLINICAL TRIALS

Highlights

- Resonance Health contracted to provide services for two new pharma customers in their clinical trials
- Value of new contracts is up to AU \$1.5m (EUR €1.0m) payable over the 28-month duration of each trial
- Resonance Health to provide its FerriScan® and Cardiac-T2* iron-overload analysis and related services
- Increases the total clinical trials currently under contract and being serviced by Resonance Health to 12

Resonance Health Contracted for Two New Clinical Trials

Resonance Health Ltd (ASX: RHT) ("Resonance Health" or "Company") is pleased to advise that it has contracted with two new pharmaceutical customers to provide FerriScan®, Cardiac-T2*, and related analysis services, for their clinical trials, increasing the number of clinical trials currently contracted and being serviced by Resonance Health to twelve. Each trial is expected to have a duration of 28 months.

Resonance Health's clinical trial services

Both clinical trials relate to the development of new drugs and/or therapies to address iron-overload disorders. Resonance Health has approximately 20 years' experience servicing the iron-overload disease market, most notably through its FerriScan® and Cardiac-T2* software-as-medical-devices ("SaMDs") which are used globally by clinicians in their management of patients with iron-overload blood disorders. FerriScan® is widely regarded as the global gold standard for the analysis of liver-iron-concentration ("LIC") and is frequently used by pharmaceutical companies in their clinical trials.

Iron overload disorders

Iron overload disorders affect millions of people globally, most notably in diseases such as thalassaemia, sickle-cell disease ("SCD") and hereditary hemochromatosis. It is estimated that over 250 million people globally¹ are gene carriers of haemoglobin diseases, with a higher prevalence of the disease in certain developing world nations that collectively comprise the "thalassaemia belt" (see ASX release dated 6 April 2022, page 10).

In January 2022, Resonance Health contracted its first Chinese pharmaceutical customer for the development of a new drug to manage thalassaemia in China and globally. Thalassaemia is especially prevalent in China, where 30-40 million people are estimated to be carrying the alpha or beta thalassemia gene (see ASX release dated 27 January 2022).² With the evolution of FerriSmart®, the Company's AI-assisted version of FerriScan®, the Company is poised to provide its service to larger markets more sensitive to price-point.

Clinical trials contract details

The first clinical trial contract is valued at up to EUR €860K and accounts for most of the combined trial value of EUR €1.0M. This trial has a duration of 28 months and includes recurring monthly imaging project management fees and variable fees that are service provision dependent. The contract may be terminated by the customer on 60 days' written notice, including where the customer determines to discontinue the trial. Similarly, the contract may be extended by the customer upon reaching agreeable terms with the Company. The customer sponsoring the clinical trial is a European Union ("EU") domiciled pharmaceutical company.

The second clinical trial contract is with a US company, and it also has an expected duration of 28 months. The total service fees are comprised of fixed and variable fees, with the variable fees comprising most of the contracted amount. The payment of the full contracted amount is contingent upon the trial continuing for its expected duration of 28 months. The customer can terminate the contract by providing 30 days' written notice to the Company and the customer can also extend the contract upon agreeing additional fees with the Company.

About FerriScan®

FerriScan® provides accurate measurement of LIC through non-invasive MRI-based technology. It is used by clinicians and patients globally in the assessment of iron overload diseases and by pharma companies in their clinical trials. FerriScan® is



recognised internationally as the gold standard in liver-iron assessment and has United States Food & Drug Administration ("FDA") regulatory clearance, as well as EU CE Mark and Australian TGA regulatory clearances.

On 25 July 2022, FerriScan®, the Company's best-selling device, was made available to clinicians globally on 3.0T MRI scanning machines (see ASX release dated 25 July 2022). Since advising clinicians of this, the Company has onboarded 34 new MRI scanners from existing and new customers, which speaks to the benefit of this production innovation. The Company can now also provide its Cardiac-T2* service on 3.0T scanners for investigational use which includes many clinical trials, depending on the customer's specific requirements.

Comment

Managing Director of Resonance Health, Mr. Mitchell Wells, commented:

"It is pleasing to contract with these new commercial customers so soon after launching our Resonance Clinical initiative. Once again, Resonance Health will be engaging in the important work of assisting pharmaceutical companies develop drugs and treatments for patients with liver diseases. Since 2005 we have provided services to dozens of clinical trials and we are currently contracted and providing services to 12, which is testament to the regard with which our medical devices and services are held. We look forward to working with our new customers and we wish them the best with their pursuit to improve the lives of people with iron-overload disorders."



**Resonance
Clinical**

Powered by Resonance Health

This announcement has been authorised for release in accordance with the delegated authority of the Board of Directors of Resonance Health Ltd.

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About Resonance Health

Resonance Health is an Australian healthcare technology and services company. The Company's services are used globally by clinicians in the management of human diseases and by pharmaceutical and therapeutic companies in their clinical trials. Resonance Health has gained endorsement by leading physicians worldwide for providing high quality quantitative assessments essential in managing diseases and drug development.

Resonance Health's dedication to scientific rigour and quality has enabled it to achieve regulatory clearances for a range of Software-as-Medical Devices (**SaMDs**) in the USA, Europe, UK, and Australia, and to proudly carry ISO 13485 certification for the design and manufacture of medical devices. Regulatory cleared SaMD products, some of which incorporate Artificial Intelligence (**AI**), include:

- **FerriScan®**, a core-lab product that provides an accurate assessment of liver iron concentration (**LIC**) through non-invasive MRI-based technology, for use in the assessment of individuals with iron overload conditions. Internationally recognised as the gold standard in LIC assessment.
- **FerriSmart®**, an AI-assisted, non-invasive MRI-based device for the automated real-time assessment of LIC in patients, calibrated against the global gold standard, FerriScan®.
- **HepaFat-Scan®**, an MRI-based solution which provides a reliable, non-invasive assessment of liver-fat in liver tissue for use in the assessment of individuals with confirmed or suspected fatty-liver-disease.
- **HepaFat-AI®**, an AI-assisted, non-invasive device for the automated real-time multi-metric assessment of liver-fat in patients, for the assessment of individuals with confirmed or suspected fatty liver disease.
- **LiverSmart®**, an AI-assisted, non-invasive MRI-based multi-parametric device combining FerriSmart® and HepaFat-AI® into a consolidated report providing accurate assessment of LIC and liver fat.
- **CardiacT2***, the most widely accepted MRI method for assessing heart iron loading. Resonance Health offers a dual analysis of FerriScan® and CardiacT2*. CardiacT2* is TGA and CE Marking regulatory cleared.

The Company has a development pipeline of additional medical imaging analysis products and services, including **CardiacT2*-AI** an AI tool for the automated analysis and quantification of cardiac-iron levels and **LungSmart (Alert-PE™)**, an AI tool for the automated review of chest CT scans of patients with suspected PE.

Stakeholders, including clinicians, patients, and shareholders, are encouraged to register their interest at www.resonancehealth.com and to follow Resonance Health on Facebook, LinkedIn, and Twitter.

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¹ "World Distribution, Population Genetics, and Health Burden of the Hemoglobinopathies, Thomas N. Williams and David J. Weatherall, *Cold Spring Harb Perspect Med* 20122:011692

² "The prevalence of thalassemia in mainland China: evidence from epidemiological surveys", Ketong Lai, Guifeng Huang, Li Su & Yunyan He, *Nature*, 19 April 2017