The Gold Study

Global Vaccine Data Network®

Implementing the gold standard suite of post-authorisation vaccine safety studies for COVID-19 and smallpox vaccines within New Zealand

To support safe vaccine delivery and public confidence in vaccination, it is imperative that detection and risk assessment of adverse events of special interest (AESI) following vaccination is carried out as close to the occurrence of the events as possible.

The Gold Study

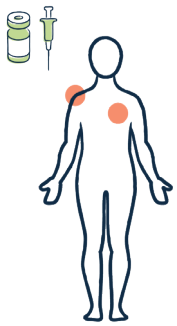
The Gold Study will use data to identify background and observed rates for 13 adverse events of special interest (AESI) and conduct rapid cycle analysis of potential AESI across the New Zealand population that can be repeated regularly. The Gold Study will also determine the risk of myocarditis and pericarditis post-vaccination in the New Zealand population, and, if statistical power is sufficient, identify how Māori and Pacific Peoples were impacted differently to other ethnic groups.

Gold Study data and analyses will be included in the Global COVID Vaccine Safety (GCoVS) project that is assessing the safety of COVID-19 vaccines across large and diverse populations using the 17-country Global Vaccine Data Network Consortium. Use of a common protocol across multiple sites increases the likelihood of identifying very rare AESI, if they have occurred, in the overall populations and will include diverse populations geographically and ethnically, such as Māori and Pacific peoples. Multi-country studies can provide an estimated risk of a rare or very rare AESI occurring among sub-populations that cannot be measured in a single country alone.

Vaccine safety surveillance

There are three levels to post authorisation vaccine safety surveillance.

The first level of surveillance is through a passive system that relies on spontaneous reporting of adverse events. While New Zealand has a very high reporting rate to the Centre for Adverse Reaction Monitoring (CARM) at the New Zealand Pharmacovigilance Centre compared with other countries (an indication of a well performing system) the population of this country is very small and rare safety events are unlikely to be detected through this system.



The second level actively looks for and verifies possible safety signals through regular monitoring of the occurrence of potential AESI across the population in near real-time as a vaccine is introduced (rapid cycle analysis), and comparison of these with the rates normally expected (background rates of the same events before the vaccine was introduced).

The third level, if a possible safety signal is identified, is assessing if there is an association between the event occurring and receipt of a vaccine (association studies). These investigations will determine if the event occurred by coincidence after receipt of the vaccine or was likely caused by the vaccine and what the risk is.

Myocarditis and pericarditis

In April 2021, a possible safety signal from an increased number of cases of myocarditis after receipt of the Pfizer/BioNTech COVID-19 vaccine (a mRNA vaccine) was identified in Israel. However, COVID-19 infection is also known to cause myocarditis.

The global response from vaccine safety experts and their organisations was unprecedented. The existing active safety surveillance activities continued while the focus on myocarditis and pericarditis post-vaccination increased, association studies were rolled out, information was shared across borders, regulatory agencies and the Global Advisory Committee on Vaccine Safety to the World Health Organization reviewed the information as it emerged, and made expert recommendations, that informed governments and subsequent immunisation policies.

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While the risk of vaccine-related myocarditis or pericarditis is low, an association between receipt of a mRNA COVID-19 vaccine and the onset of myocarditis or pericarditis was established in many populations around the world.

The onset of myocarditis after receipt of one of the earlier generation smallpox vaccines has also been well-documented. However, much less is known about the safety of the newer Jynneous vaccine as the total usage experience was in about 10,000 individuals in clinical trials, where myocarditis was not seen but troponin elevations were reported. Emergence of mpox (previously monkeypox) and the planned New Zealand introduction of Jynneous vaccination for people at increased risk of exposure to mpox, prompted a Gold Study addendum that utilises the protocols developed to assess COVID-19 vaccine safety to assess the safety of the Jynneous vaccine within New Zealand.

The genomics of adverse events

Through the Gold Study, New Zealand will also be able to make a unique contribution to a global study examining genetic contribution towards vaccine-related adverse events, particularly a genetic association between receipt of a mRNA vaccine and the onset of myocarditis or pericarditis. Genomic investigations may be able to inform who is at risk of a specific adverse event as well as lead to a better understanding of the biological or pathophysiological basis of adverse events. Genetic contributions to serious and life-threatening drug reactions have already seen genetic information incorporated into 800 drug data sheets worldwide by regulators.

For more information

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About us

The Global Vaccine Data Network™ (GVDN®) constitutes a multinational network of sites conducting globally coordinated active surveillance epidemiologic studies of the safety and effectiveness of vaccines. The GVDN network currently consists of 24 partners across 18 countries and is expanding. Through international collaboration with capacity for data linkage, it is now possible to have a large enough population to conduct robust analyses of very rare events following vaccination.

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