

GARDASIL®

A GLOBAL SOLUTION TO REDUCING CERVICAL CANCER

From its origins in ground-breaking research at The University of Queensland, to its use in more than 130 countries, the Gardasil® cervical cancer vaccine has led to an up to 90 per cent decrease in the prevalence of human papilloma virus in countries with high levels of immunisation.



When the research of Professor Ian Frazer and the late Dr Jian Zhou at The University of Queensland (UQ), led to a vaccine for the virus that causes many cervical cancers, they knew the work was going to be transformative. The result was the vaccine, Gardasil®, designed to protect both women and men against the human papilloma virus (HPV).

THE DISCOVERY

The Gardasil® story began at UQ in 1990 when molecular virologist Dr Jian Zhou joined Professor Ian Frazer at UQ to tackle the problem of developing a vaccine for HPV.

They used technology to make virus-like particles that could mimic HPV. These particles structurally resemble viruses but are non-infectious because they do not contain any viral genetic material.

The vaccine, Gardasil®, works by introducing virus-like particles into the body, activating the body's immune response and protecting against future infection from HPV. Cancer of the cervix is a serious disease and the second biggest killer of women worldwide. HPV is known to cause more than 70% of cervical cancers and 90% of genital warts worldwide.

There are many different types of HPV and most people who have HPV may not show any signs or symptoms, meaning that they can unknowingly pass the virus to others. While the majority of people are unaffected and go on to clear the virus, those who do not can develop cervical cancer, precancerous lesions or genital warts. HPV is also linked to the development of cancers of the anus, penis, mouth and throat.



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IMPACT

UniQuest, UQ's main commercialisation company, worked hard to bring Gardasil® to the world, providing support through a long-running and costly patent dispute after competing American researchers filed a patent application for a vaccine essentially the same as the UQ invention.

After almost a decade of sales, Gardasil® continues to dominate the global HPV vaccine market, achieving more than US\$15 billion in gross product sales between 2007 and 2016.

Gardasil® is now available in more than 130 countries and more than 200 million doses have been distributed around the world. Thanks to the efforts of Professor Frazer, and support from the Gates Foundation and the World Health Organisation, the vaccine has been made available to developing countries at a low cost, with UniQuest waiving its right to royalty payments from sales in developing countries.

In Australia, the federal government has funded the provision of free vaccines available to all teenaged girls from 2007. This program was extended to include teenaged boys from 2013. In the 10 years since the vaccine's release, the infection rate of HPV has lowered by up to 90 per cent in countries with high levels of immunisation, with similar decreases in genital warts and cervical abnormalities also reported.

PATENT PROTECTION

- 1991** UniQuest filed a provisional patent application on the HPV technology. Three days later, the UQ researchers presented their preliminary findings at a conference in Seattle, USA.

- 1992** UniQuest submitted a complete patent application.

- 1994** UniQuest's patent application came up for patent examination by the US Patent and Trademark Office. The patent examiner queried if the US university had invented the vaccine first.

- 2007** After a long-standing court action, the US Federal Court ruled in favour of the UQ patent application confirming it had the earlier priority date. A contributing factor was that the lead researcher from the US university had attended the 1991 Seattle conference where the UQ researchers presented their research.

GARDASIL®

COMMERCIALISATION AND CLINICAL TRIALS

Research continued at UQ following the 1991 patent application and, in 1994, UniQuest licensed the intellectual property to CSL Limited in Melbourne, Australia. CSL funded further research and development and continued to involve Professor Frazer in the HPV vaccine development.

In 1996, CSL sub-licensed the HPV technology to Merck & Co., Inc. (known as Merck Sharp & Dohme outside the US and Canada), retaining the rights to market the technology in Australia and New Zealand. In 2005, CSL entered into a cross-licensing and settlement agreement with GlaxoSmithKline for its cervical cancer vaccine product, Cervarix®, which also used the UQ technology.

Merck & Co., being one of the largest pharmaceutical companies in the world, was an ideal commercialisation partner for the long and large human clinical trials. The phase three clinical trial involved more than 12,000 women, aged 16–26, from 13 countries.

The result of the trial showed women in the vaccine group had a significantly lower occurrence of high-grade cervical intraepithelial neoplasia related to HPV-16 or HPV-18 than those in the placebo group. The clinical evidence was so strong that, before the study was completed, it was halted on ethical grounds to enable the young women on placebo to receive Gardasil®.

The Federal Drug Administration in the United States approved Gardasil® in 2006 and it was launched onto the global market. FDA approval for GlaxoSmithKline's Cervarix® followed in 2009.



PROFESSOR IAN FRAZER

UQ Research Strength:
Immunology and infectious diseases

UQ Innovators:
Professor Ian Frazer
and the late Dr Jian Zhou

UQ Faculty Or Institute:
UQ Diamantina Institute

UQ Research Outcome:
Virus-like particles of HPV
used as a vaccine

UniQuest IP Position:
A number of patent applications

UniQuest Partnering:
R&D collaboration and license
agreement with CSL

UniQuest Commercialisation:
License to CSL sub-licensed to Merck &
Co and cross-licensed to GlaxoSmithKline

THE GARDASIL® JOURNEY SO FAR

- Gardasil® works by introducing virus-like particles into the body that activate the body's immune response, protecting against HPV infection.
- After a long and costly patent dispute, the patent application filed by UniQuest in 1991 was ultimately granted by the US Federal Court in 2007.
- In 1994, the HPV program was licensed by UniQuest to CSL in Melbourne, Australia, and the intellectual property rights later sub-licensed from CSL to Merck & Co., Inc.
- Merck & Co. funded the phase three clinical trial involving more than 12,000 women aged 16–26 from 13 countries.
- Gardasil® was approved by the FDA in 2006.
- Gardasil® is now available in more than 130 countries with more than 200 million doses distributed around the world.
- Co-inventor Professor Frazer was named Australian of the Year in 2006, named a National Living Treasure in 2012 and received a Companion of the Order of Australia in 2012.
- In December 2014, following a clinical trial, the FDA approved the next-generation 9-valent vaccine Gardasil 9, which protects against additional high-risk HPV types.
- In 2015, Professor Frazer and the late Dr Zhou were awarded the Popular Prize at the European Patent Office's Annual European Inventor Awards.

PARTNER WITH UNIQUEST

UniQuest is Australia's leading university commercialising entity, specialising in commercialising the intellectual property of The University of Queensland.

- We have created more than 80 companies from our intellectual property portfolio.
- Together with our start-ups, we have raised more than A\$600 million to take university technology to market.
- UQ technologies licensed by us – including UQ's cervical cancer vaccine technology and image technology in magnetic resonance imaging equipment – have resulted in more than \$US15.5 billion in gross product sales.
- We have been granted 87 US patents and have more than 200 active license agreements.

If you want to know more about this commercialisation story or other offerings from UniQuest, contact:

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