

GARDASIL®

A GLOBAL SOLUTION TO ERADICATING CERVICAL CANCER

From its origins in groundbreaking research at The University of Queensland, to its use in more than 130 countries worldwide, the Gardasil® cervical cancer vaccine has led to an approximately 90 per cent decrease in the prevalence of human papillomavirus (HPV), the major cause of cervical cancer.



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 most 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 human papillomavirus (HPV).

THE DISCOVERY

The Gardasil® story began in 1990 when molecular virologist Dr Jian Zhou joined Professor Ian Frazer at UQ to tackle the problem of developing a vaccine for HPV. Together they used technology to make virus-like particles that could mimic HPV. Virus-like particles structurally resemble viruses but are non-infectious because they do not contain any viral genetic material.

HPV is known to cause more than 70 per cent of cervical cancers and 90 per cent of genital warts worldwide. There are many different types of HPV and most people who carry HPV may not show any signs or symptoms, meaning that they can unknowingly pass the virus to others. While many people are unaffected and go on to clear the virus, those who do not can develop cervical cancer, precancerous lesions or genital warts. Cancer of the cervix is a serious disease and the second biggest killer of women worldwide.

The Gardasil® vaccine works by introducing virus-like particles into the body, activating the immune response, resulting in protection against future infection from HPV.

“ 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. ”

IMPACT

UniQuest, UQ’s commercialisation company, helped to make Gardasil® available to the world, providing support through a long-running and costly patent dispute.

After almost a decade of sales, Gardasil® continues to dominate the global HPV vaccine market, achieving more than \$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. In addition, the improved Gardasil 9 HPV vaccine, which still relies on the UQ intellectual property, in 2018 secured FDA approval in China and expanded approval in the United States.

Through the implementation of the Gardasil® vaccine, cervical cancer is set to become a rare disease by 2020 and so uncommon by 2028, that Australia is hopeful of becoming the first country in the world to eliminate the disease.



GARDASIL®

THE PATH TO COMMERCIALISATION AND CLINICAL TRIALS

UniQuest filed the initial patent applications in 1991. Research continued at UQ following the 1991 patent application and, in 1994, UniQuest licensed the intellectual property to CSL Limited in Melbourne, Australia, with the goal of CSL developing the vaccine clinically. 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 (GSK) 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 required for the vaccine to be approved for humans. The phase three clinical trials involved more than 12,000 women aged 16–26, in 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 (FDA) in the United States approved Gardasil® in 2006 and it was launched onto the global market for human use.

FDA approval for GSK's Cervarix® followed in 2009.



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
for use in the approved vaccine

UniQuest IP Position:
A number of patent applications
granted

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

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

PROFESSOR IAN FRAZER

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 intellectual property was licensed by UniQuest to CSL Limited 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 in 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, a National Living Treasure in 2012 and received a Companion of the Order of Australia in 2012.
- 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 100 companies from our intellectual property portfolio.
- Together with our startups, we have raised more than A\$700 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 \$US16 billion in gross product sales.
- We have been granted 87 US patents and have more than 200 active licence agreements.

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

E: enquiries@uniquest.com.au

W: uniquest.com.au