



Intercytex

Accelerated approval for breakthrough therapies: streamlining clinical development

World Stem Cell and Regenerative Medicine Congress
21st May 2013

Paul Kemp CEO & CSO Intercytex

EMA

FDA

AFSSPS (France)

Singapore Health Sciences Authority

Health Canada

MIT

Harvard Medical School

Novartis

AstraZeneca

Bristol-Myers-Squibb

Johnson & Johnson

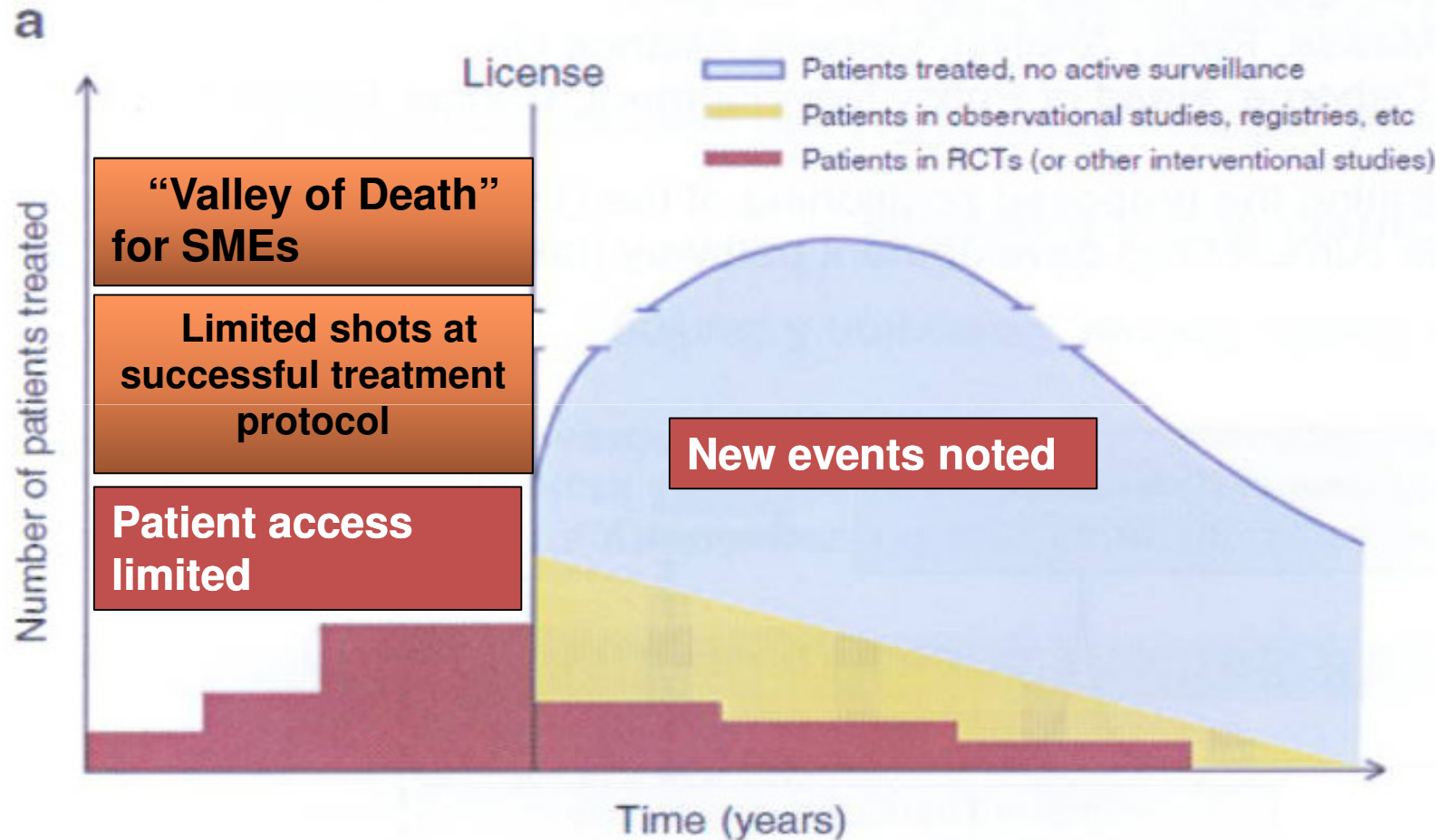
Pfizer

Aetna

Friends of Cancer Research

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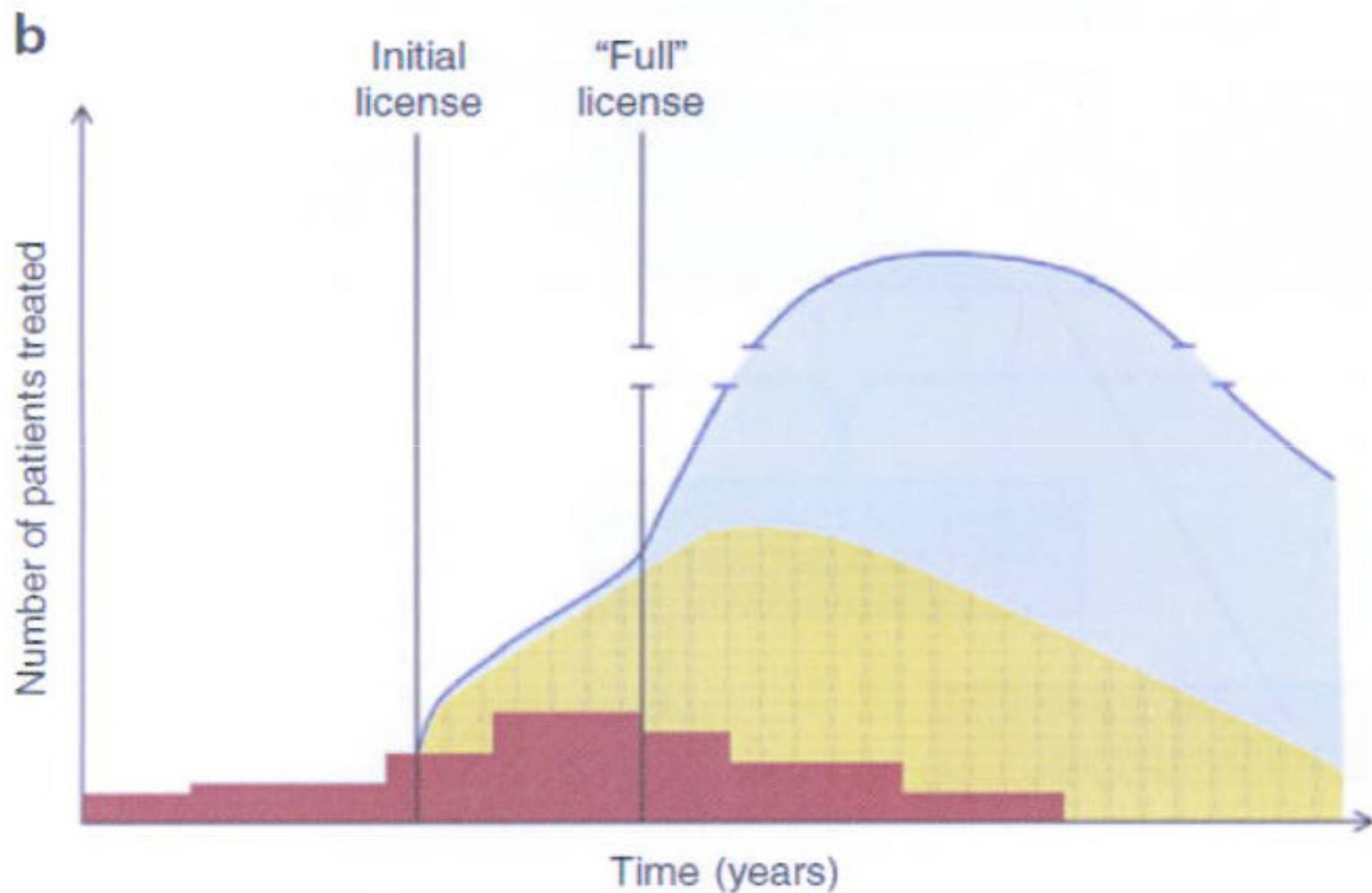


Current Licensing system

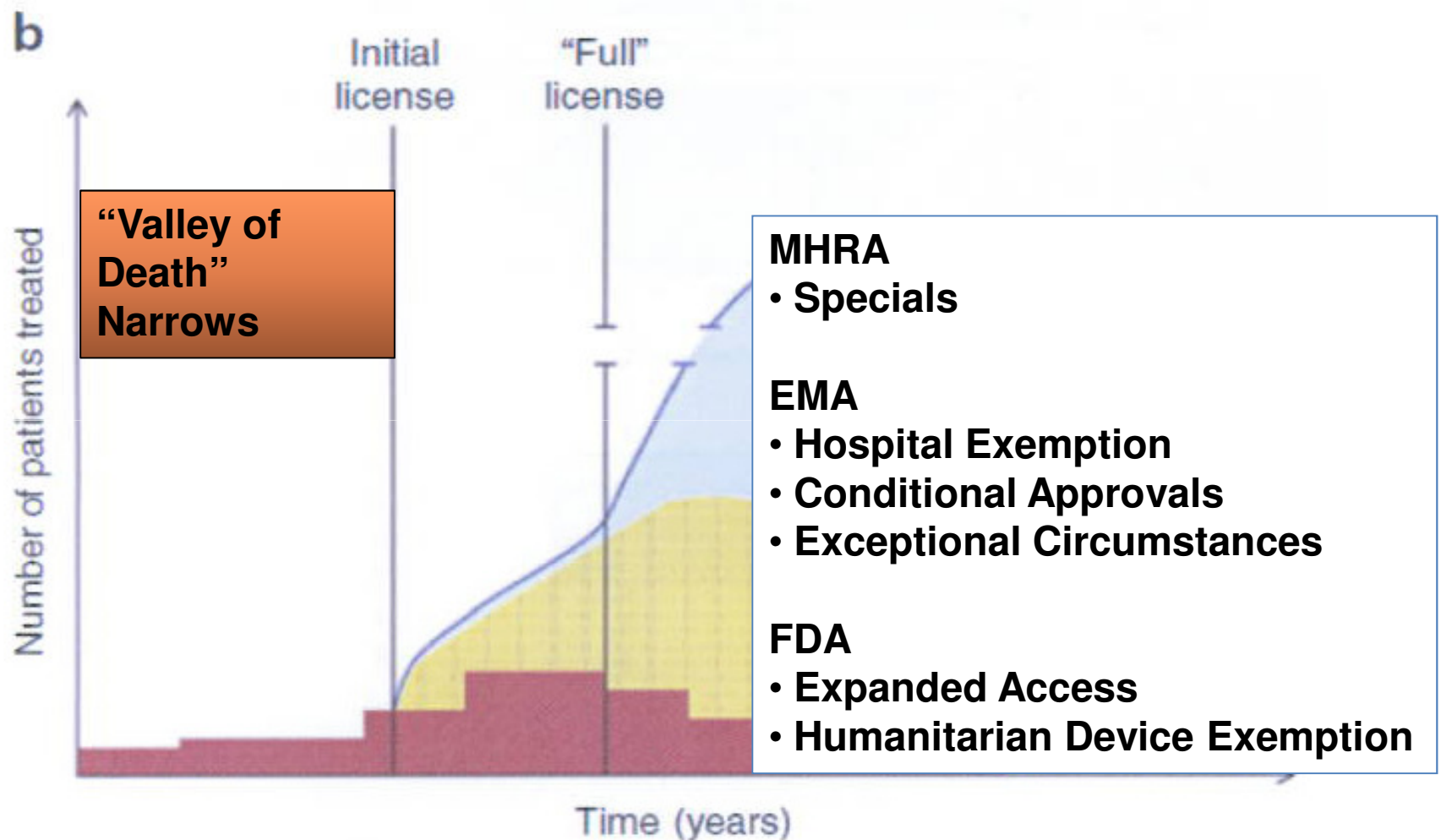
“The current standard pathway to market access is ill-suited to enable timely, well-informed patient access, stimulate drug development, and simultaneously ensure routine collection and evaluation of all relevant Information on benefits and risks”

“Costs of medicines are increasing and there are few truly innovative treatments. As a result, the rising cost of incremental gains in health benefits is unsustainable within the environment of strained budgets”

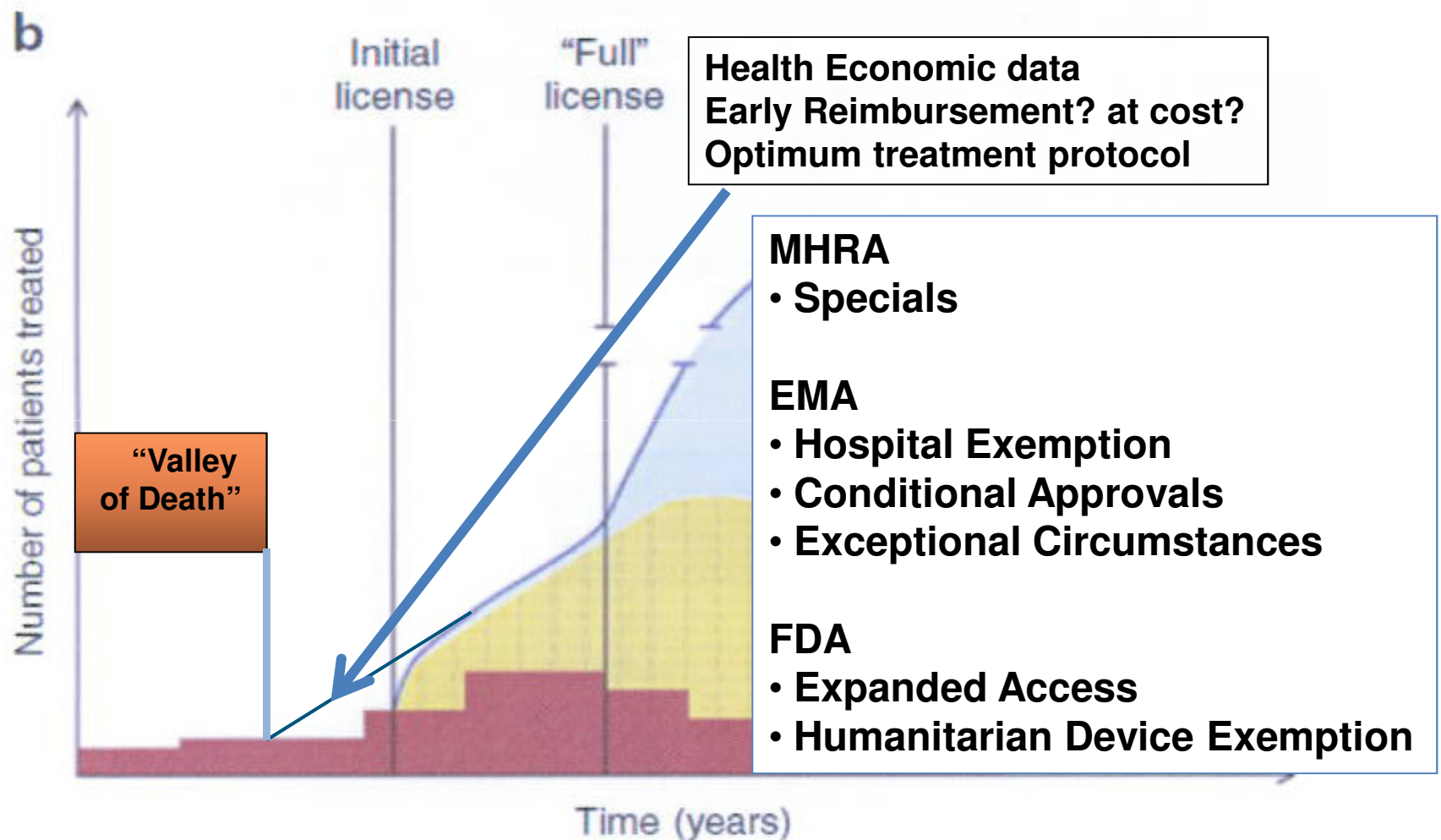
Conditional Approval Licensing



Conditional Approval Licensing



Progressive Translation



Overview



Need for regulation:

- ✓ Protect public health
- ✓ Regulatory clarity and certainty
- ✓ Encourage innovative in patients' interests

Tissue engineering characteristics :

- ✓ Small spin off companies and specialist hospitals
- ✓ Small scale production
- ✓ Iterative development - gradual emergence of efficacy; procedure or product?
- ✓ Gradation of risk

Progressive Translation



- **Progressive Licensing: Focus on unmet medical need and orphan products in order to allow access to the current legislative frameworks already in place of conditional approvals.**
- **Progressive Development : A close partnership between client, contract developer and hospital allowing iterative development of new treatments.**
- **Progressive Reimbursement: Obtain early reimbursement from a variety of sources that will both help development finances as well as providing critical marketing information**

To do this, we are:

- **Using Vavelta/ICX-RHY as exemplar**
- **Developing collaboration/partnership with NHS Teaching Hospital**
- **Utilising specials and clinical trial routes in parallel**
- **Improving product, manufacture and delivery**
- **Obtaining reimbursements from various sources**

ICX-RHY / VAVELTA®



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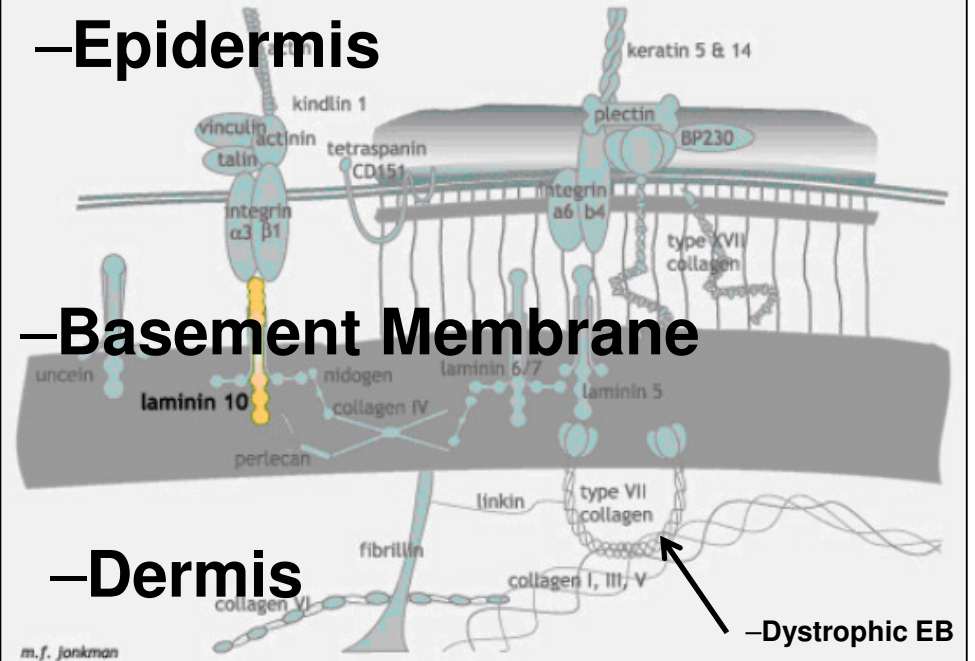
ICX-RHY Medical applications: EB



–Epidermis

–Basement Membrane

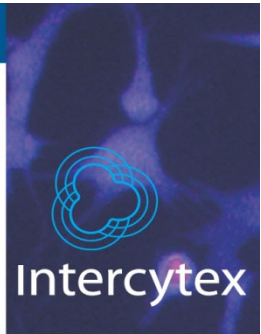
–Dermis



Results from Patient 14



“Just after a week of treatment I began to notice improvement in my very large back wound. Although it hasn't fully healed yet it, it has significantly shrunk in size and the healed areas around the wound are much stronger now as they do not blister as they used to and the wound, almost a year on is continuing to heal, something that it has not done in the last fourteen years.”



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