



Award-winning, ISO13485 certified medical device company

Health Tech Event

Vanessa Vankerckhoven, CEO & Co-Founder

April 25, 2019

Career path

MSc Biomedical Sciences (2000)

PhD Medical Sciences (2009)



Project Manager EU Projects

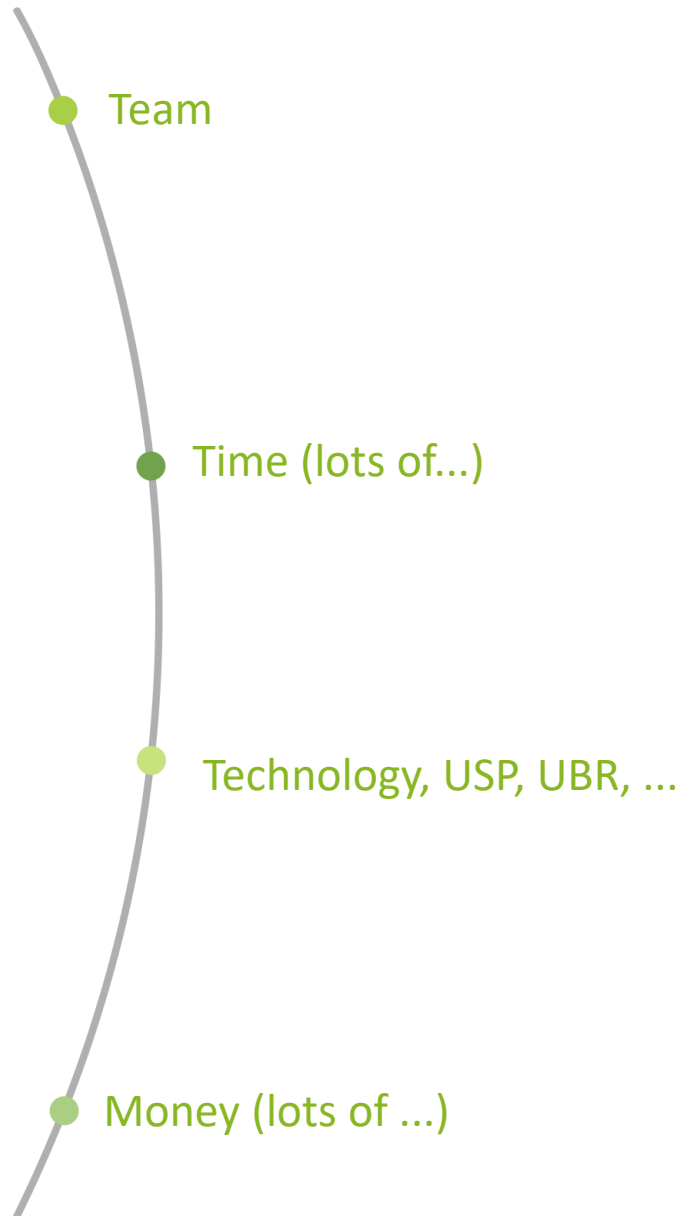
Innovation Manager



CEO & Co-Founder of Novosanis



Any ideas for medical devices?





VD Vaccine &
Infectious
Disease
Institute

 **artesis**
productontwikkeling

voxdale® 

Multidisciplinary approach

The start of Novosanis



12 MARCH 2013



From table to in-house production



*DCDW, Lange
Winkelhaakstraat 26,
Antwerp*




*Former Toshiba Medical building
Bijkhoevelaan 32c, Wijnegem*

2018



From an R&D driven to a Sales driven organisation

- 
- **Team of 15 (22)** – Design & Engineering, Regulatory affairs, Clinical affairs, Quality, Operations, Manufacturing, ...
 - **Raised money** - 3M€ dilutive + 3M€ non-dilutive
 - **Validation & Market feedback rule** – Evolution from an R&D environment to Sales organisation
 - **Quality rules too** – Quality system, ISO 13485



OraSure Technologies, Inc.



4 JANUARY 2019

Novosanis, a wholly owned subsidiary of OraSure Technologies Inc. (NASDAQ: OSUR)

Vision

"Novosanis envisions a world without infectious diseases and cancer"

Mission

"Novosanis aims to improve the quality of diagnostic tests as well as the accuracy of drug delivery for infectious diseases and oncology."



improving the quality of
diagnostic tests for infectious diseases
and oncology.

”

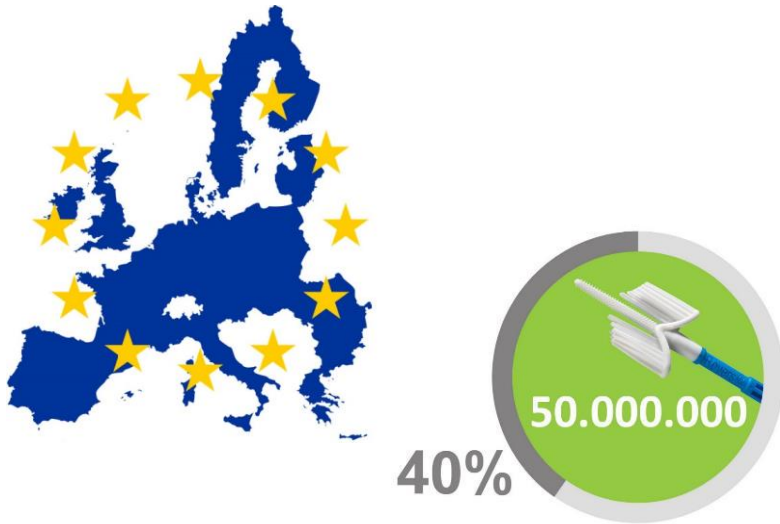
 Colli-Pee™

First void urine as an alternative to Pap smears for HPV testing



Shift cytology-based screening to HPV-based primary screening

M. Arbyn (personal communication); RIVM; FIT market research



20M unscreened women (25-64 years) in EU28 alone

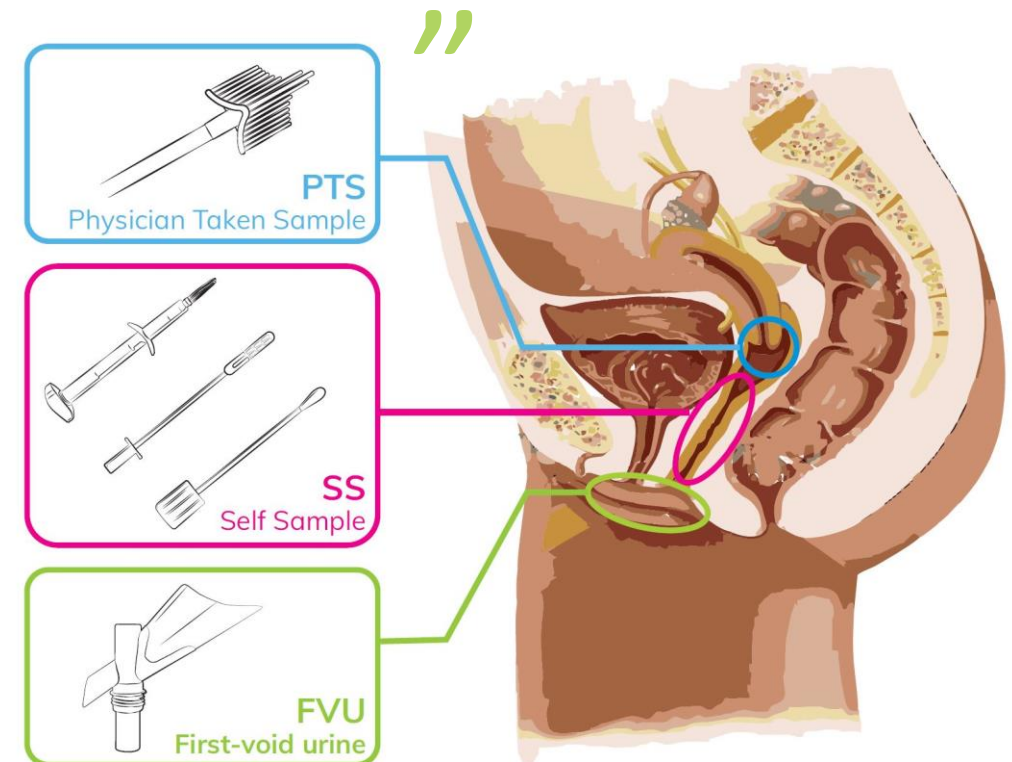
WHO statistics on cervical cancer, FIT market research

Cervical cancer is still the 4th most common cancer in women despite proven efficacy of screening programs.

Stewart et al 2014

Colli-Pee was equally sensitive in detection of CIN2+ as physician-taken smears

Leeman et al BJOG 2016



Challenges for Dx assays and lab handling

- Error prone
- Lack of standardization & accuracy
- Lack of guaranteed first-void urine (first catch = first 20ml of the urine flow)
- Lack of ease of use

STEP 1 | First-void urine collection by patient



STEP 2 | Transfer of urine in preservative and/or smaller tube



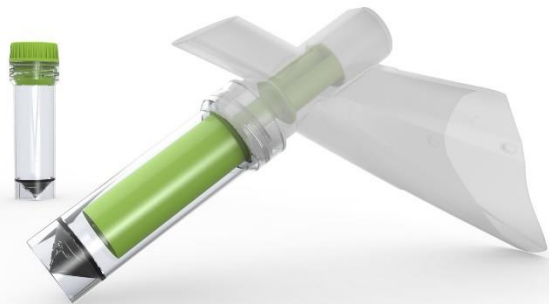
STEP 3 | Molecular analysis



Solutions for Dx assays and lab handling

- No errors due to automated mixing of urine & preservative (if applicable)
- Standardization & accuracy
- Guaranteed first-void urine (first catch = first 20ml of the urine flow)
- Ease of use

STEP 1 | First-void urine collection by patient



STEP 2 | Transfer of urine in preservative and/or smaller tube



STEP 3 | Molecular analysis



Saltro Directlab

EEN INITIATIEF VAN SALTRO

[Contact](#) | [Voor huisartsen](#)



Mijn winkelwagen

[Over SOA's](#)

[Testwijzer](#)

[Webshop](#)

[Hoe werkt het](#)

[Uitslag](#)

[Vragen](#)

[Over Saltro Directlab](#)



Chlamydia test voor de man

€ 31,50

In winkelwagen



Test makkelijk en snel of u chlamydia heeft. Voor de test is ochtendurine - de zogenoemde eerste straal urine - nodig. Na afname stuurt u de test veilig via de post naar het laboratorium van Saltro. U ontvangt de uitslag snel en discreet.

[Meer informatie](#)

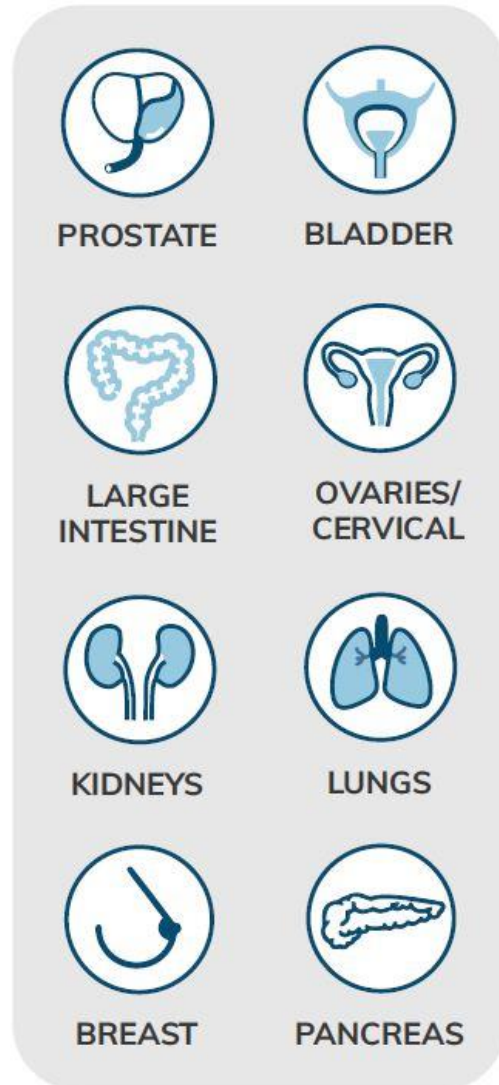
Uw voordelen

- ✓ Snel
- ✓ Makkelijk
- ✓ Betrouwbaar
- ✓ Discreet

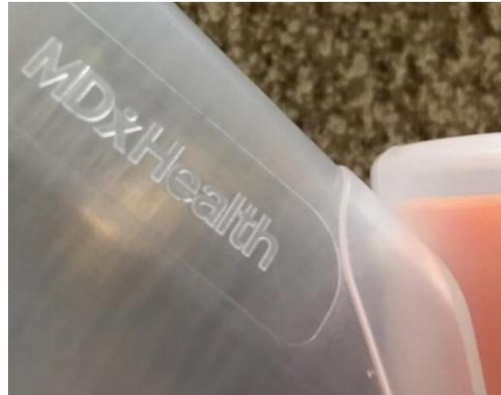
Hoe werkt het?

- 1 Vul de testwijzer in
- 2 Bekijk ons advies
- 3 Bestel via de webshop
- 4 Voer zelf de test thuis uit
- 5 Stuur de test terug naar Saltro DirectLab
- 6 Bekijk online de uitslag

First void urine as a liquid biopsy for oncology



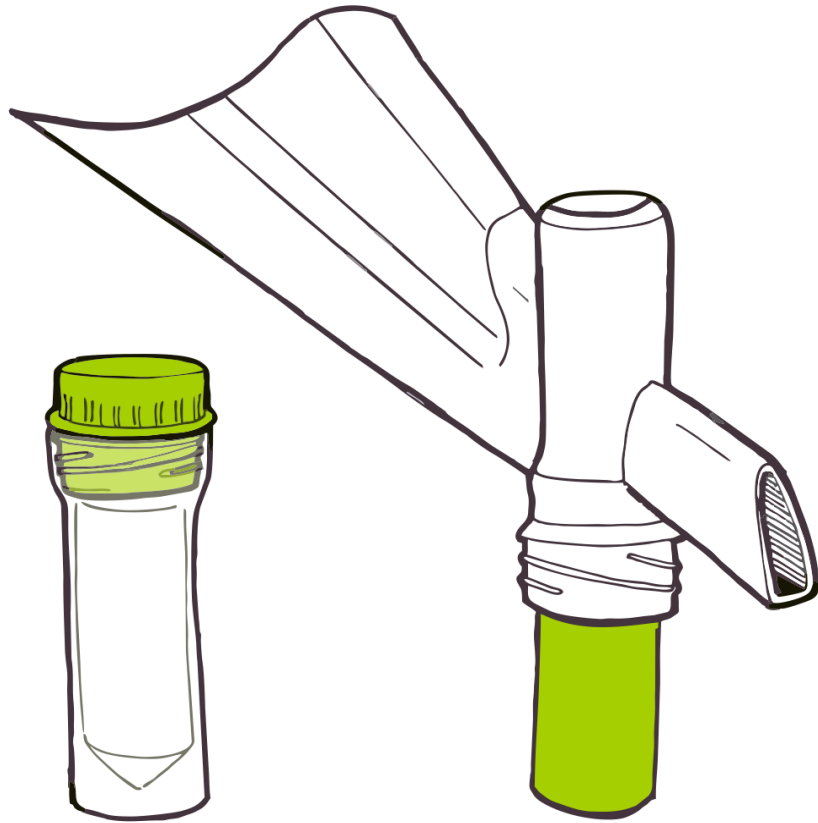
Customer MDxHealth **SelectMDx** for Prostate Cancer



MDxHealth.
Select **MDx**[®]
for Prostate Cancer



From idea to device



Follow-up of HPV vaccination



User needs:

Non-invasive sampling

Follow-up HPV vaccination

Idea:

First-void urine

Product Definition

Intended use

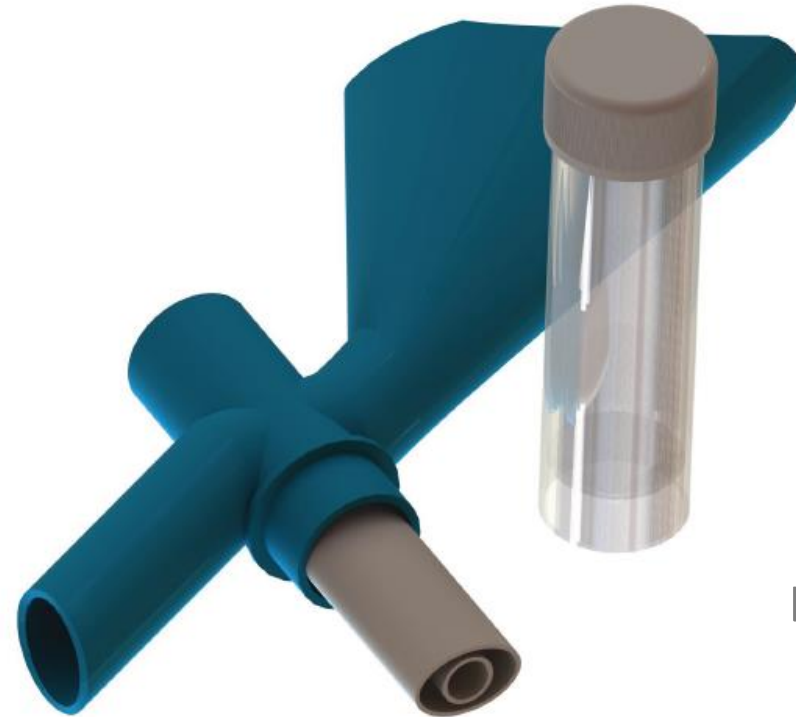
Guaranteed collection of first-void urine

Design drivers:

Collection first 20ml

Home-based sampling

Postal delivery

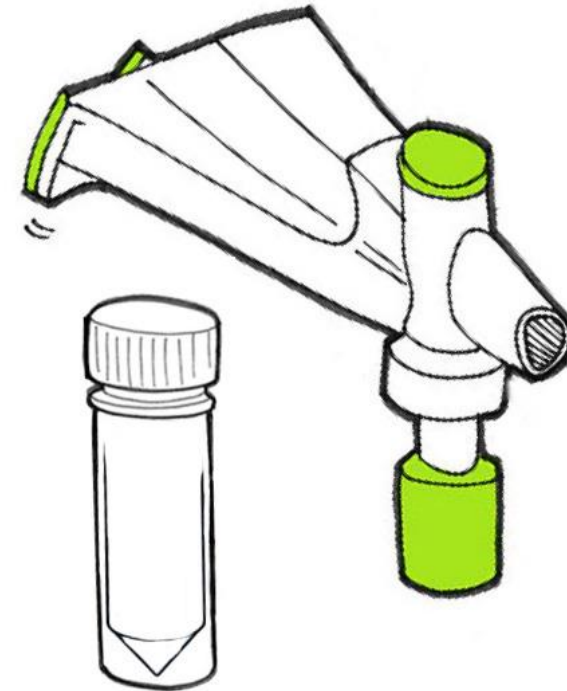


“Pi²”

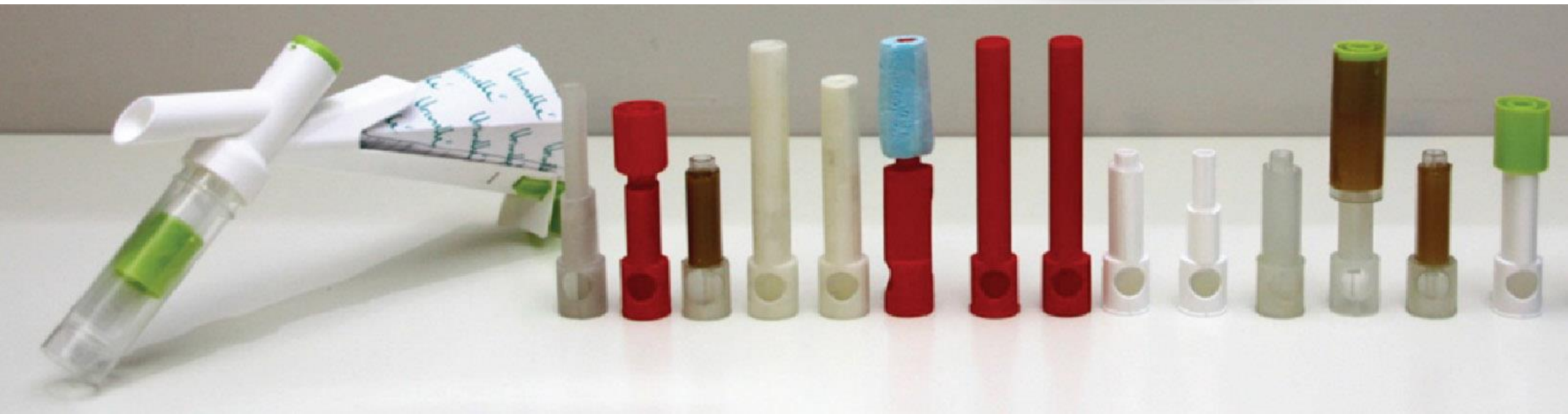
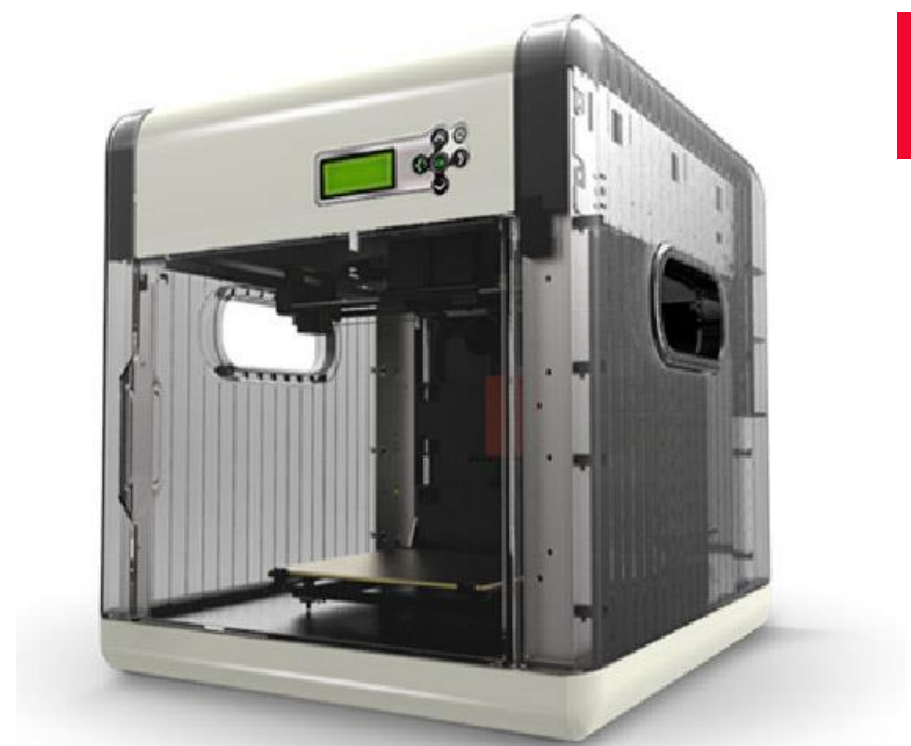
Lara Biekens

“2Pi” BiR&D

Hanne De Bauw
Ragnar Dienske
Tina Van Hove



Creativity, innovation, prototyping technologies, ...







COLLI-PEE CP-2000 Series



COLLI-PEE FV-5000 Series



UCM-Preservative

COLLI-PEE FV-5000 Series
containing preservative

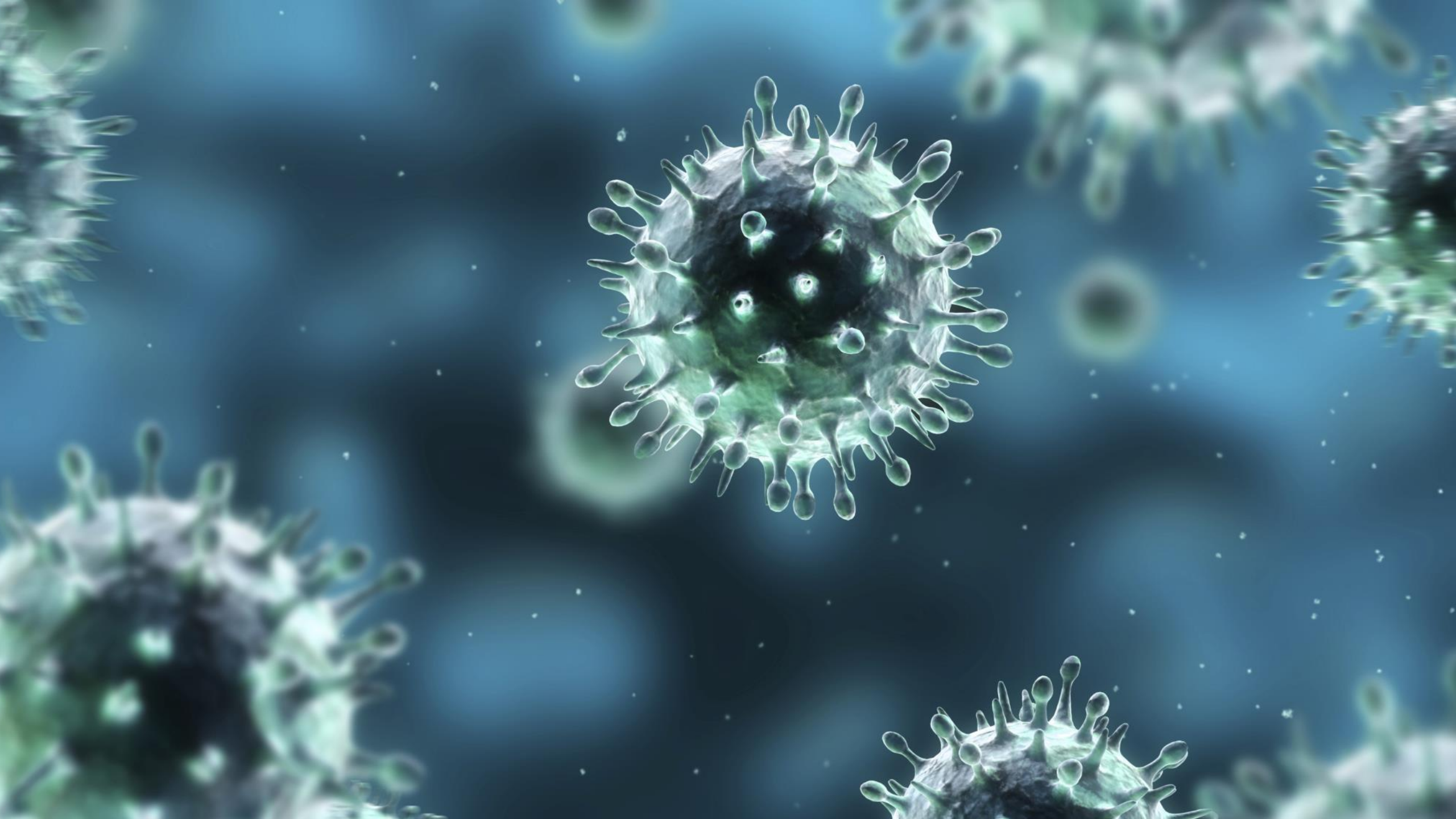




Improving intradermal drug delivery
and overall patient comfort.

vax-ID™

”



Use of traditional Mantoux technique* for intradermal injection?

Challenge 1: Leakage & Loss of expensive dose through lack of accuracy

Challenge 2: High inter-user injection variability

Challenge 3: Pain

**Current state-of-the-art intradermal injection method characterized by a needle inserted at a 10–15 degree angle, approximately 1 mm deep into the dermis, to inject a vaccine or drug.*

“VAXINTRADERMAL”

Wouter Coemans



“VAX-ID” BiR&D

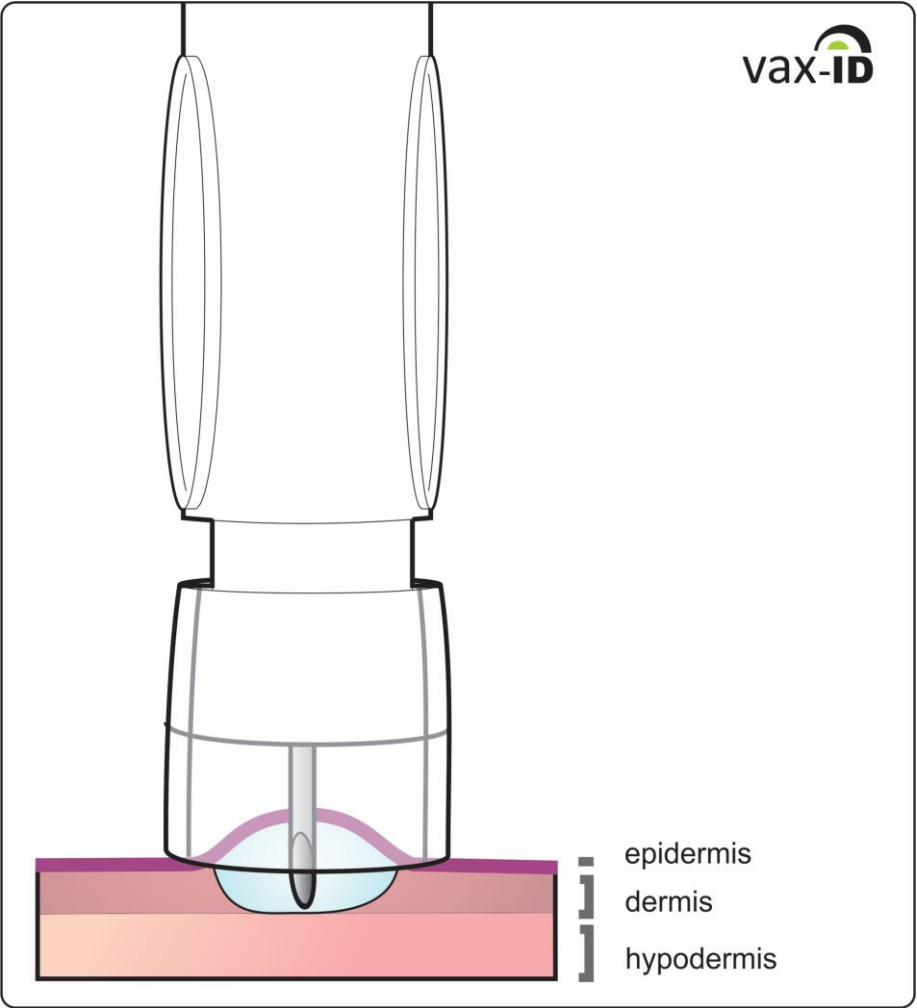
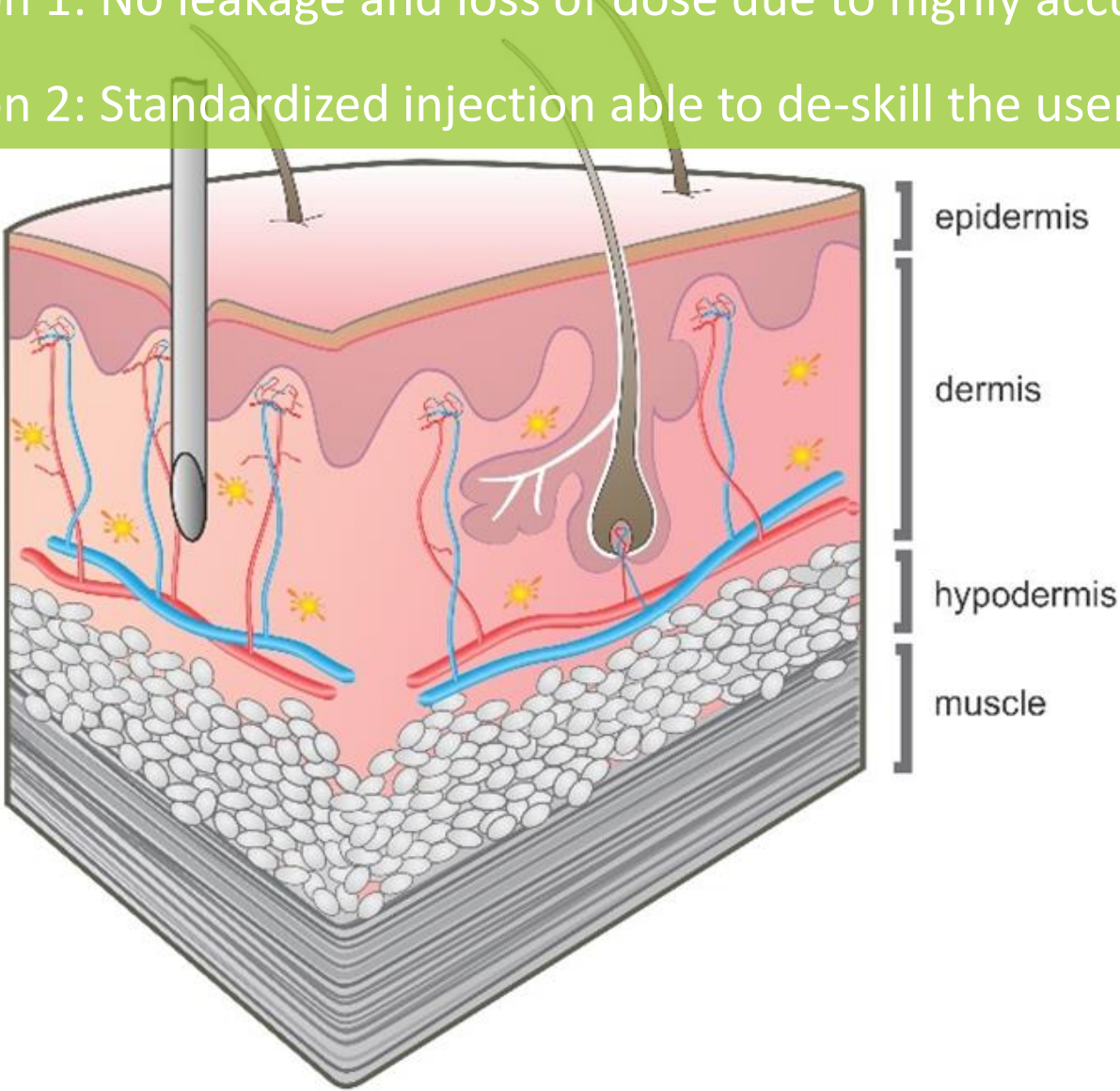
Timothi Van Mulder
Charlotte Reypens
Ruben Camerlynck



VAX-ID drug delivery platform

Solution 1: No leakage and loss of dose due to highly accurate penetration depth and volume delivery

Solution 2: Standardized injection able to de-skill the user and de-risk clinical trials





PCT/EP2013/057990

VAX-ID Prefilled Series

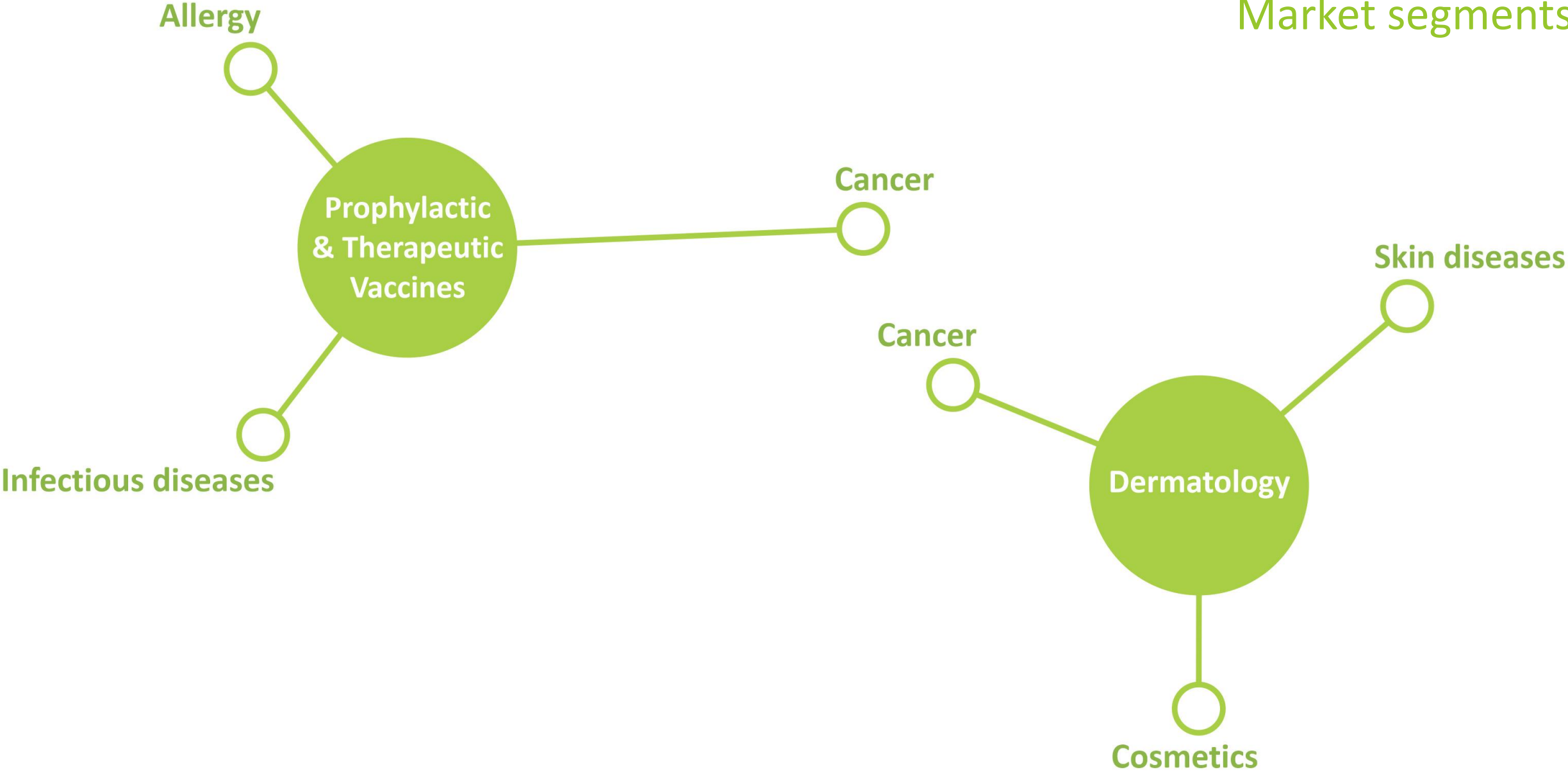
**JAMES
DYSON
AWARD**



VAX-ID IDE2000 Series



Market segments



Key achievements



13485:2016



Agência Nacional
de Vigilância Sanitária



Comisión Federal para la Protección
contra Riesgos Sanitarios



COLLI-PEE
PIDIC
VAX-ID

AGENTSCHAP
INNOVEREN &
ONDERNEMEN

LYO-ID



Vlaanderen
is ondernemen



VALPAS



PEE-POST
INJECT-ID



CASUS



In house assembly in Class D clean area (ISO 13485)



HENRY VAN
DE VELDE
AWARD 17

HEALTHCARE

COLLI-PEE

VOXDALE FOR
NOVOSANIS NV



But don't forget...

Cheers!

Urine good hands.





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