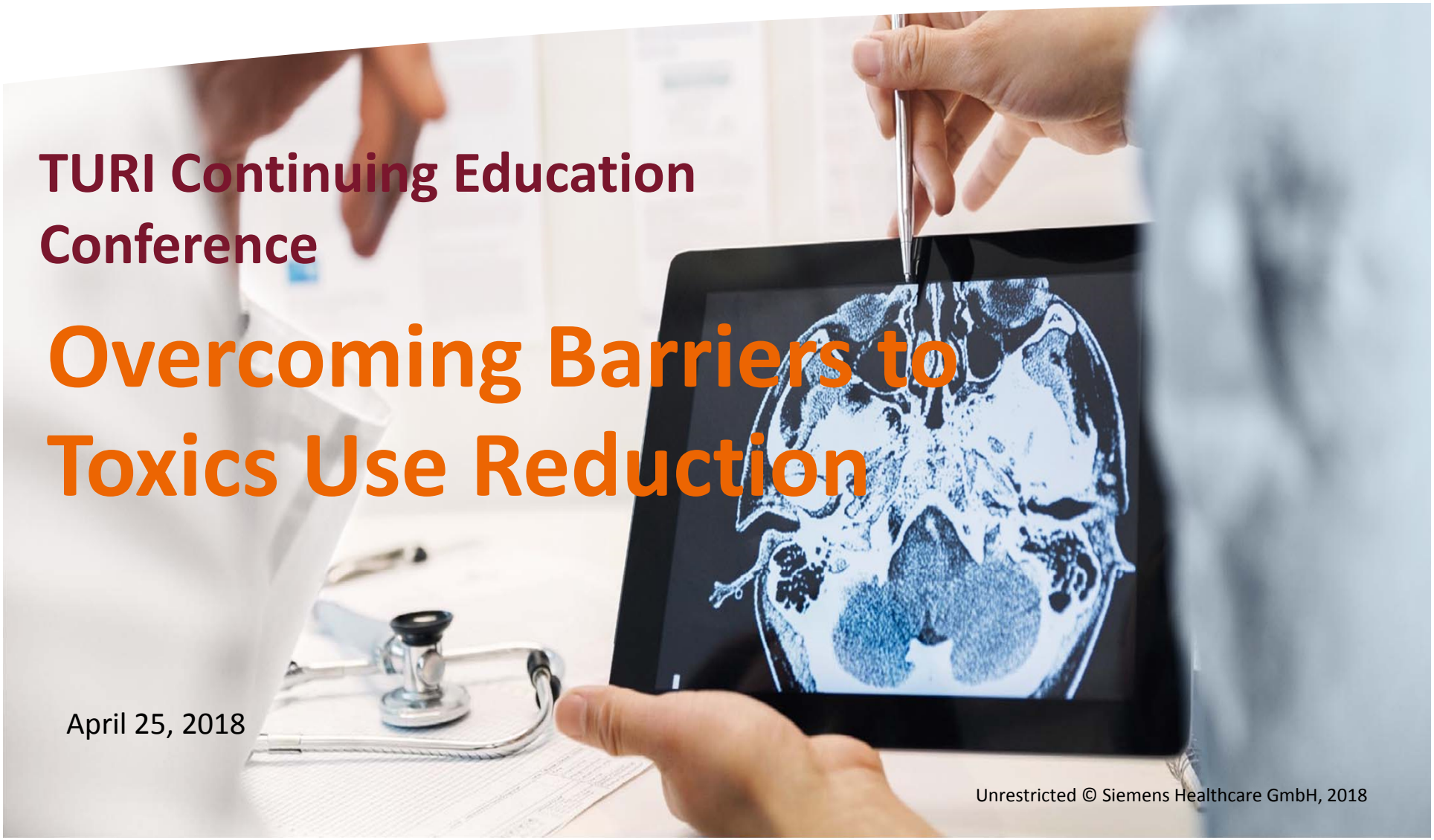
SIEMENS Healthineers



TURI Continuing Education Conference

Overcoming Barriers to Toxics Use Reduction

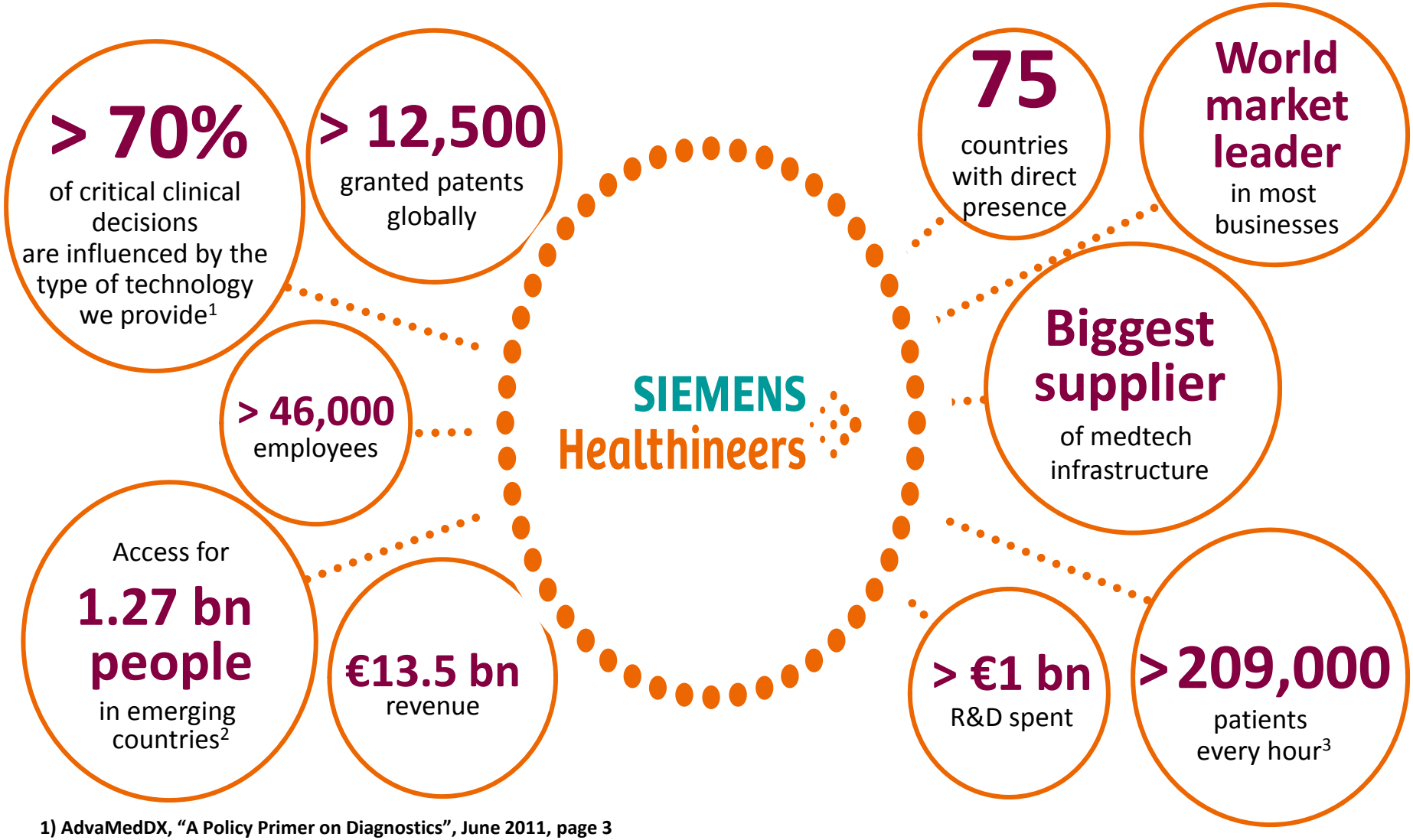
April 25, 2018

Overview

- Siemens Healthineers
- TURI-Siemens OPE replacement project
- Barriers encountered
- Path forward and anticipated challenges
- Summary/Q&A

Engineering success. Pioneering healthcare.

Who We Are



1) AdvaMedDX, "A Policy Primer on Diagnostics", June 2011, page 3

2) Siemens AG, "Sustainability Information 2016", page 8

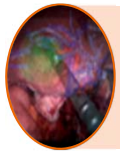
3) Siemens AG, "Sustainable healthcare strategy - Indicators in fiscal 2014", page 3-4

Engineering Success – With Broadest and Deepest Portfolio

SIEMENS Healthineers

Diagnostic Imaging
Computed Tomography, Magnetic Resonance Imaging, Molecular Imaging, Radiography & Fluoroscopy, Imaging IT

Undisputed market leader in diagnostic imaging



Advanced Therapies
Cardiology, Interventional Radiology, Radiation Oncology, Surgery

Empowering innovative therapy concepts

Ultrasound
Cardiology, Radiology

Versatility and functionality across clinical questions

Laboratory Diagnostics
Immunoassay, Chemistry, Hematology, Hemostasis, Specialty Testing, Automation, IT and Services, Molecular Diagnostics[1]

Delivering clinical and workflow excellence

Point of Care
Blood Gas, Diabetes Urinalysis, Coagulation, Cardiology

Lab-accurate, actionable, timely results at the point of care

Services
System Services, Education, Enterprise Services, Digital Services

Transformative services to maximize opportunities and minimize risks

We support to raise …

- **clinical excellence**
- **operational efficiency**
- **financial profitability**

1) Incubated within Business Function Strategy & Innovation
Image courtesy Diagnostic Imaging: CMRR, Minneapolis, MGH, Boston
Image courtesy Advanced Therapies: IHU Strasbourg, France

Sustainability is part of our company's culture and our company's success

We have acted sustainably for 170 years…

"I won't sell the future for short-term profit"

Werner von Siemens

While hazardous substances are still needed for Medical Devices, **we believe that removing or replacing them**

→ Is important for protection of our employees and the planet
→ Makes good business sense
→ Is the right thing to do!

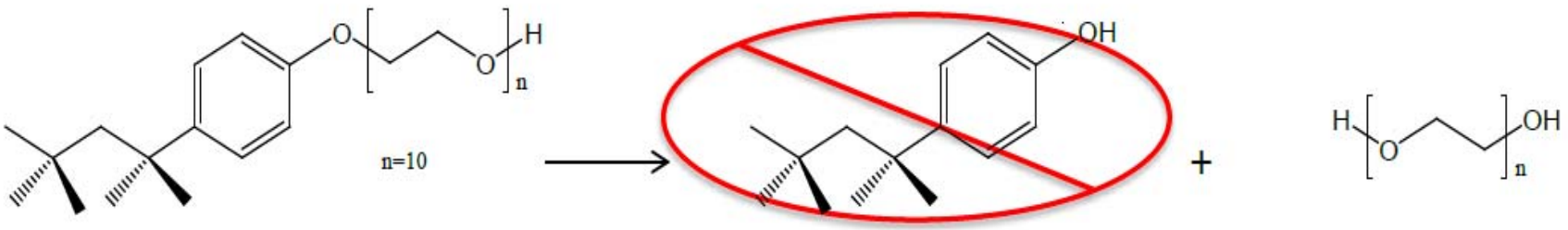
The “Triton” Challenge

EU REACH regulation designated a family of surfactants as Substances of Very High Concern (SVHC)- octylphenol ethoxylates (OPEs- under trade names Triton X-100, X-405, Igepal)

Used in the invitro diagnostics (IVD) industry for many years- once viewed as a *safe* alternative

OPEs are Substances of Very High Concern (SVHC):

- Degrade to octylphenol, which is persistent, bio-accumulative and known to act as a hormone endocrine disruptor and estrogen mimics



Octyl phenols Ethoxylates

Triton X-100™

Octylphenols

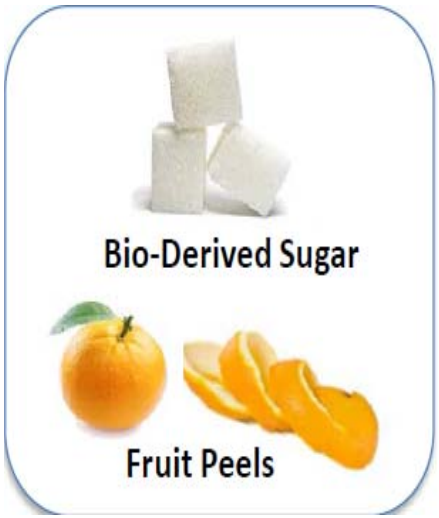
Polyethylene Glycol

Collaboration with TURI, UMass and Siemens

Academic research grant provided framework for a solution

Project with UMass and TURI for a solution:

- Siemens had the need and desire for a long-term, **"greener-safer"** answer
- **TURI** had expertise in toxics alternatives along with funding for research
- **UMass** already had experience with OPE substitutes
- UMass also has expertise with toxicity and biodegradation testing



Resulted in two alternatives (oligopectin and octyl glucoside):

- Derived from **renewable starting materials**
- From an efficient, **greener synthesis**
- With acceptable **technical performance**
- **Low toxicity**
- Good **biodegradability**

Problem solved…

…not so fast

Challenge	Impact
Technical/performance	Performance variations among different assays
Regulatory processes (e.g. FDA)	Regulatory requirements mean verification, validation and possibly even clinical trials and re-registrations in multiple countries- months to years
Internal resources	One more project competing with R&D and manufacturing resources
Scale-up for manufacturing	Shift from a lab to manufacturing supplier
Risk management	“Guaranteeing” the change won’t have to be made again (e.g. no surprises in toxicity/environmental fate later on)

Next Steps

Gain confidence that the new substances are **long-term solutions:**

- ✓ UMass did extensive toxicity testing with great results
- ✓ Reviewed toxicity and biodegradation data with EPA Safer Choice group- positive feedback

Licensing agreement and work with UMass to **identify a manufacturer**

Implement strategic approach- use in new products in order to:

- **Optimize performance** (technical challenges)
- ✓ **Align resources with existing efforts** (no duplication of efforts)
- ✓ **Minimize regulatory efforts** (already needed for new products)

Still- there is a need for improving environmental and toxicity testing models to reduce risks in the long-term **(green stays green!)**

Questions?

SIEMENS Healthineers

SIEMENS Healthineers

Thank you for your attention!

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