

# Interreg



EUROPEAN UNION

# North-West Europe

# Codex4SMEs

European Regional Development Fund



Centre for Research in Medical Devices

# WestBIC





**Welcome**

# **Codex4SMES Double Session Information and Networking Event**



**Galway  
Ireland**



## Codex4SMES Double Session Information and Networking Event

**Wednesday 18<sup>th</sup> September 2019**

**Hotel Meyrick, Galway, Ireland**

### **Wednesday 18<sup>th</sup> September 2019: Hotel Meyrick, Galway City**

**0900:** Welcome and introductions

**0905:** Introduction and overview of Interreg Codex4SMEs project and the supports for SMEs - **Dr Margot Jehle, Lead partner, Codex4SMEs**

**0920:** Pathway to regulation and market for IVD Companies and start-ups: **Diarmuid Cahalane, Metabolomic Diagnostics**

**0940:** How to convince the investor to invest in your SME: **Ultan Faherty, Halo Business Angel Network.**

**1000:** The transfer of diagnostics tests from "bench to bedside" **John O'Loughlin, Rotunda Hospital**

**1030:** Tea break and parallel networking **Part 1**

**1100:** Evaluation of how different IVD's perform from clinical prospective **Dr Fergus Mc Carthy, Obstetrician, Cork University Maternity Hospital**

**1130:** Engagement with Pharmaceutical Companies **Len Marshall, Access and Innovation Manager, Roche Diagnostics**

**1200:** Questions and discussion.

**1230:** Lunch

**1300:** Networking **Part 2**

**1400:** Overview of funding access and sustainability of projects within European environment **Jeanette Mueller, Acceloment**

**1430:** Networking **Part 3**

**1500:** Finish

# The Transfer of Diagnostic Tests From Bench to Bedside

John O Loughlin, Laboratory Manager,  
Rotunda Hospital

# The Rotunda Hospital

- Founded in 1745 by Bartholomew Mosse – Innovator
- Delivering care for women and babies for nearly 275 years.
  - Oldest working maternity hospital in the world.
- In 2018 we delivered 8,486 babies
  - Rotunda one of the busiest Maternity Hospitals in Europe.
- Laboratory opened in 1896
- Member of the RCSI hospital group with strong clinical and academic links.

# History of the Rotunda



# History

- Handel's Messiah – 1742 Fishamble Street, Dublin
- Countess Markievicz – 1927
- RCSI – 1784
- First c-section – 1889
- Irish Vounteers – 1913
- GPO - 1916

# Rotunda Today



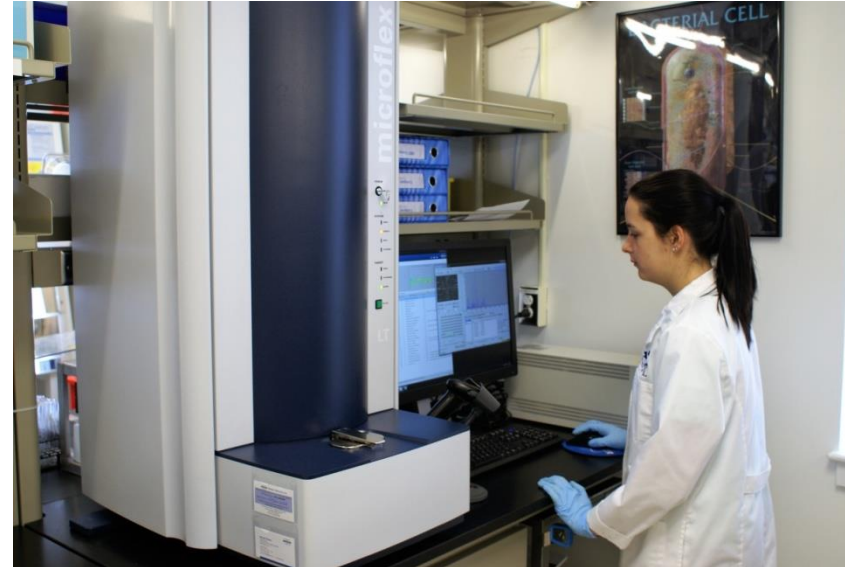


# Extremely Dynamic Environment

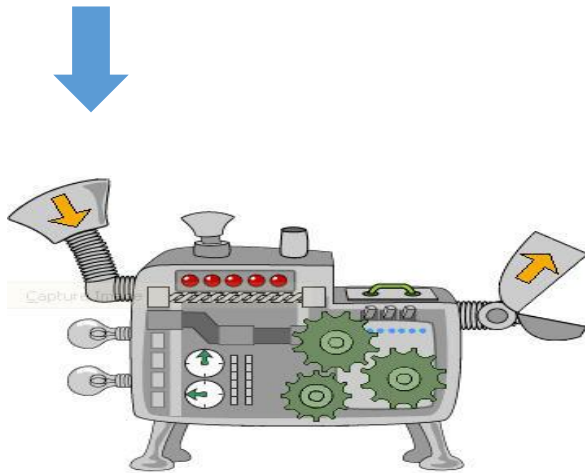
2016



2017



# Medical Laboratory – What do we do?



# Clinical Laboratory

- -ology
- Heavily regulated and accredited usually to ISO15189 by INAB, UKAS (UK), CAP (USA) etc.
- Other standards include ISO22870, ISO 9001, ISO 17025 .....
- Increasing workload in terms of scale and scope of tests delivered 24/7

# New Tests / Products

- Where do they come from?
  - Research – internal / external peer reviewed publications etc.
    - IL-6 – early detection of sepsis
  - Practice changes local/national/international
    - cffDNA (cell free foetal DNA), Sepsis pathways, Rotunda Umbifunnel
  - Business Case / Clinical case
    - Influenza, GBS (Group B Streptococcus)
  - Driven by manufacturers
    - sflt-1/plgf ratio (soluble fms-like tyrosine kinase 1 : placental growth factor ratio)

# Obstacles to Implementation

- Cost
- **Fear of Litigation**
- Ease of Use
- Clinical Governance – who is responsible for the result?
- Turn-around-time
- Physical infrastructure – need for additional equipment
- Performance - calibrations and controls
- Reliability – know, describe and quantify the limitations of your test / product
- Ease of verification / validation , IQ, OQ, PQ
- History

# Costs of Implementation

- Cost of implementing a new test
  - New instrumentation, new interface, new staff, new training, reagents, cost benefit analysis, opportunity costs, hidden costs, pricing model ...
  - Consider the pricing model carefully and have flexibility i.e. Reagent deal, capital purchase, price per test model etc.

# Costs - future

- There will be a future slowdown in health spending. Spending cannot continue increasing at the rate observed in the past, lest it rise to a ratio of output that is fiscally unsustainable or, over the long run, to a ratio exceeding 100 percent of GDP. Spending as a share of GDP has increased 6 percent to 12 percent in advanced economies and 3 to 5 percent in emerging economies (OECD).
- **Public Procurement rules!!!**

# Fear of Litigation



- In cervical cancer screening the standard has been set at 'absolute confidence' in the result – is this even possible?



# Turn Around Times (TAT)

- Is the TAT appropriate for the patient population?
- Can the test be performed 24/7?
- What kind of maintenance is required (scheduled/unscheduled downtime)?
- After sales care? Engineers, contingency plans for down time.

# Size Matters!

- Labs always stuck for space
  - Driven by increased need for sample storage
  - Increased throughput – increased footprint of bigger analysers
  - Low priority in hospitals as not a patient area
  - Often in spaces not originally designed for laboratory
  - Space lost to non-lab based activity - accreditation, IT, POCT, haemovigilance and surveillance scientists

# Ease of Validation/Verification

- **Accreditation**

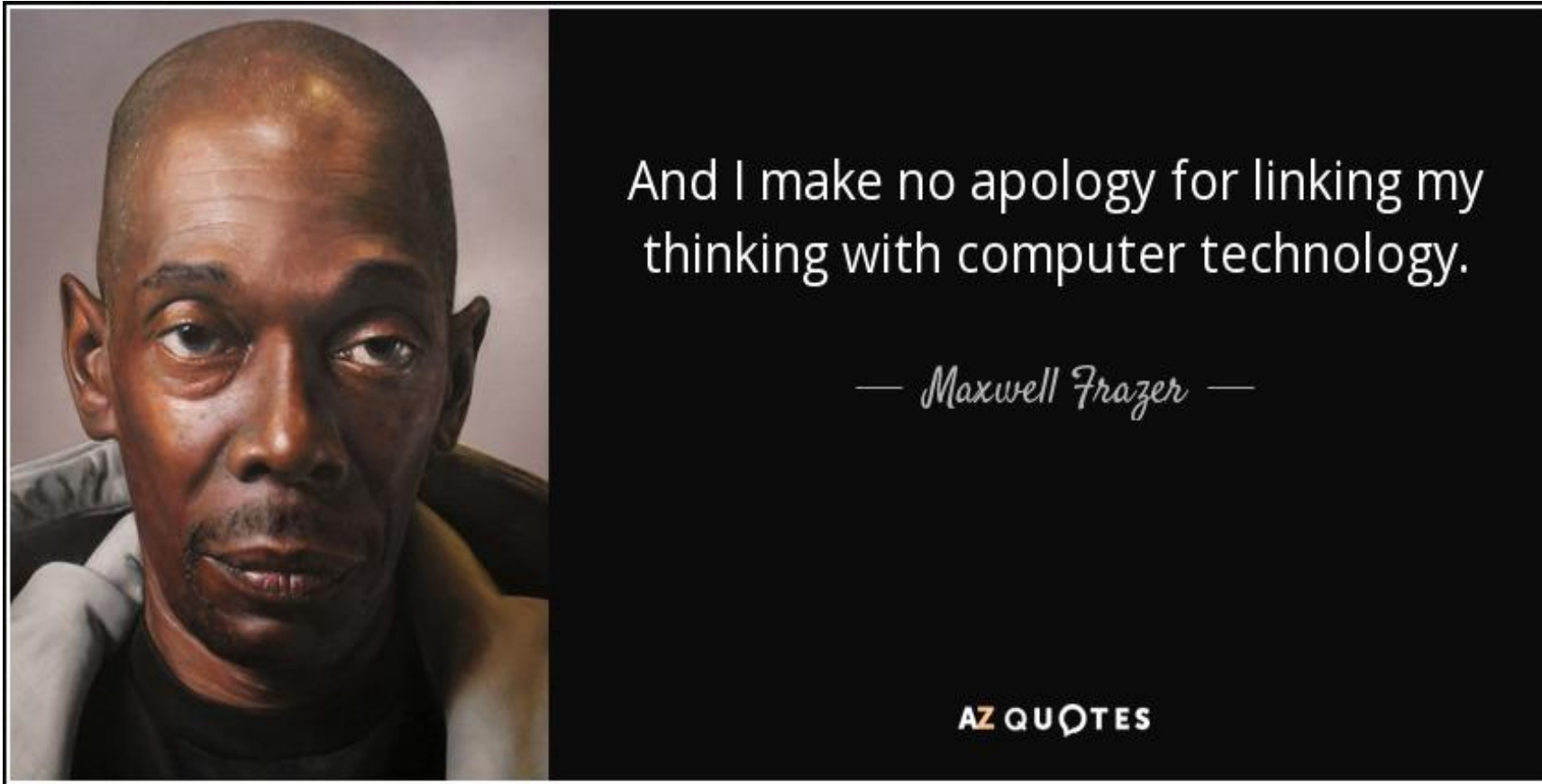
- **Validation**

- 5.5.1.1 – The laboratory shall select examination procedures which have been validated for their intended use.
    - 5.5.1.2 – Validated examination procedures used without modification shall be subject to independent verification by the laboratory before being introduced into routine use. .... The independent verification by the laboratory shall confirm, through obtaining evidence that the performance claims for the examination procedure have been met.

- **Verification**

- 5.3.1.2 – The laboratory shall verify upon installation and before use that the equipment is capable of achieving the necessary performance .....

# Ease of Use – Interface (HL7)



And I make no apology for linking my  
thinking with computer technology.

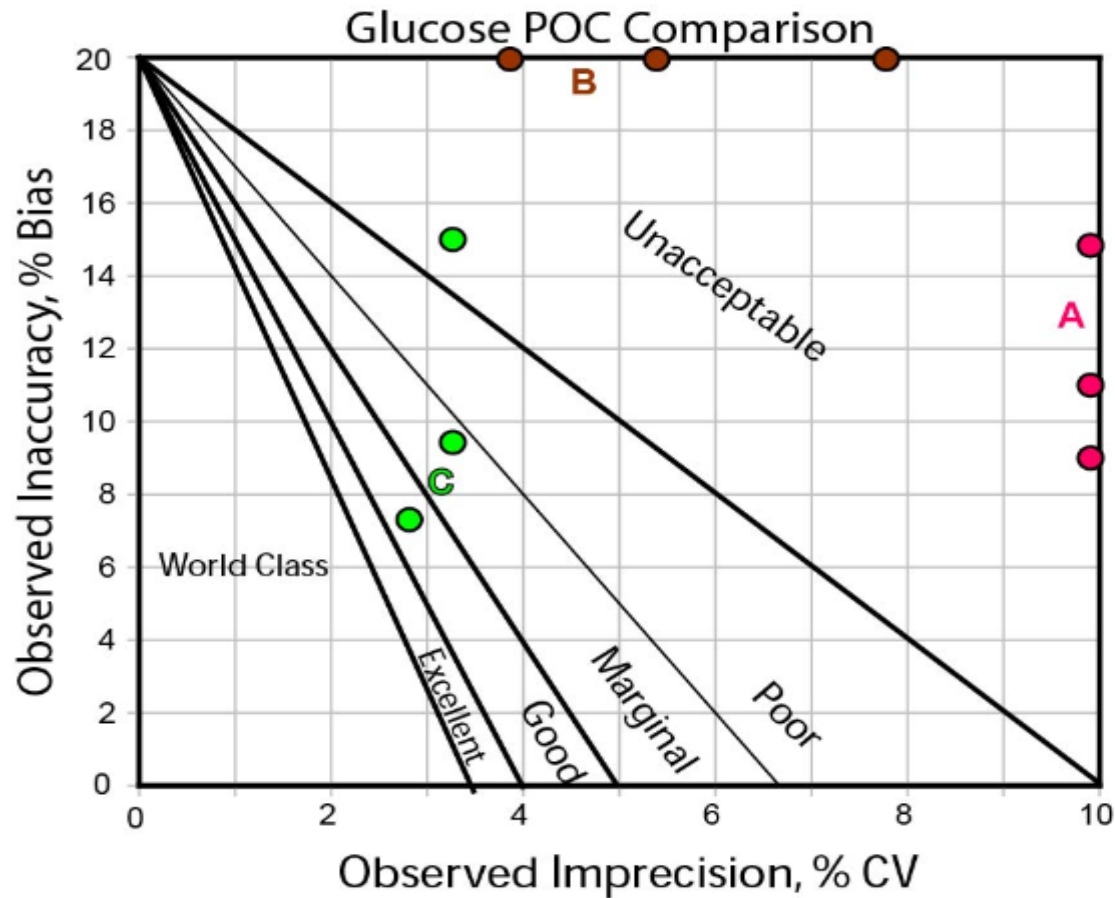
— *Maxwell Frazer* —

AZ QUOTES

# Example - design



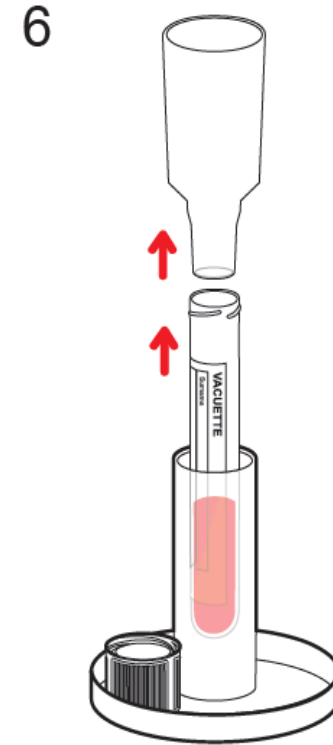
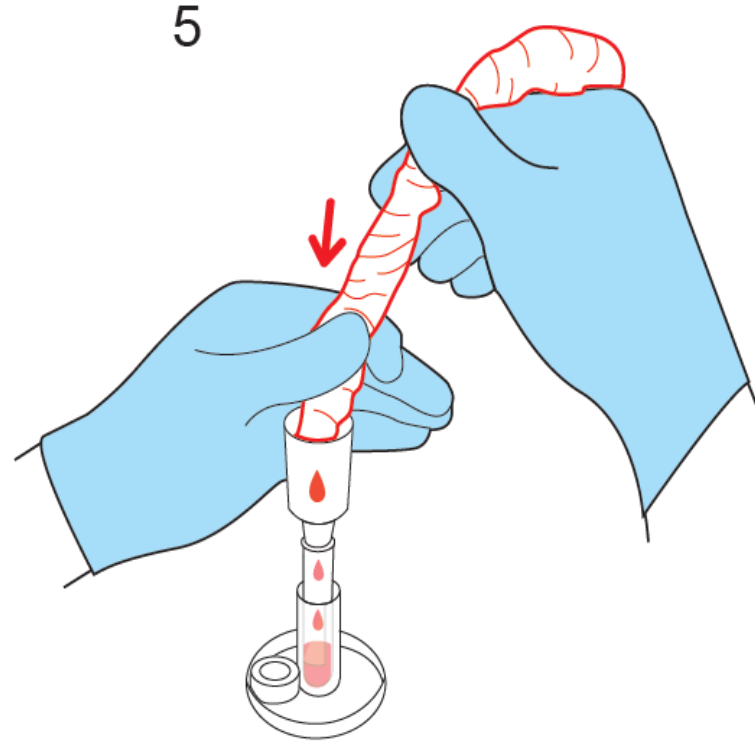
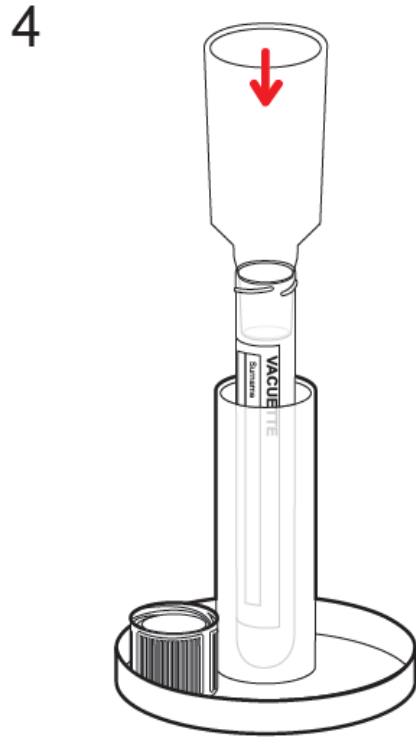
# Example – Performance Six Sigma Metrics, IQC



# Example – TAT and Ease of Use



# Example – User Resistance, Rotunda Umbifunnel





# -omics

- Translational gap: progress in translating molecular-biology breakthroughs into clinical practice ('bench to bedside') is slow.
- Truly innovative development of drug therapy in obstetrics leading to drug approval has not occurred in many years.
- The pregnant women differs in many aspects from the non-pregnant patient. Not only are there longitudinal physiologic changes that effect drug pharmacokinetics, but the genetic make-up of the foetus differs from that of the mother.

# 1877 Blood Tx

- A.K, aged 30, was admitted on Tues 6<sup>th</sup> February at 1.30am.
- Delivered at 4pm on the 8<sup>th</sup> Feb – no complications.
- After 30mins a steady stream of blood was noted. Could not stop it and by 5.45 pm the patient state was described as alarming. She then settled after injecting a solution of perchloride of iron.
- Attempted a blood transfusion. She sadly ‘sank’ and died at 10pm.

# Cautionary Tale

ANNALS OF INNOVATION DECEMBER 15, 2014 ISSUE

## BLOOD, SIMPLER

One woman's drive to upend medical testing.



By Ken Auletta



One afternoon in early September, Elizabeth Holmes took the stage at TEDMED, at the Palace of Fine Arts, in San Francisco, to talk about blood. TEDMED, a part of the Technology, Entertainment, and Design enterprise, is an annual conference devoted to health care; its speakers span a range of inquiry from Craig Venter, the genomic scientist, discussing synthetic life, to Ozzy Osbourne discussing his decision to get his entire genome sequenced. The phrases "disruptive technology" and "the future of



Elizabeth Holmes says that her test can help detect ailments from just a few drops of blood.

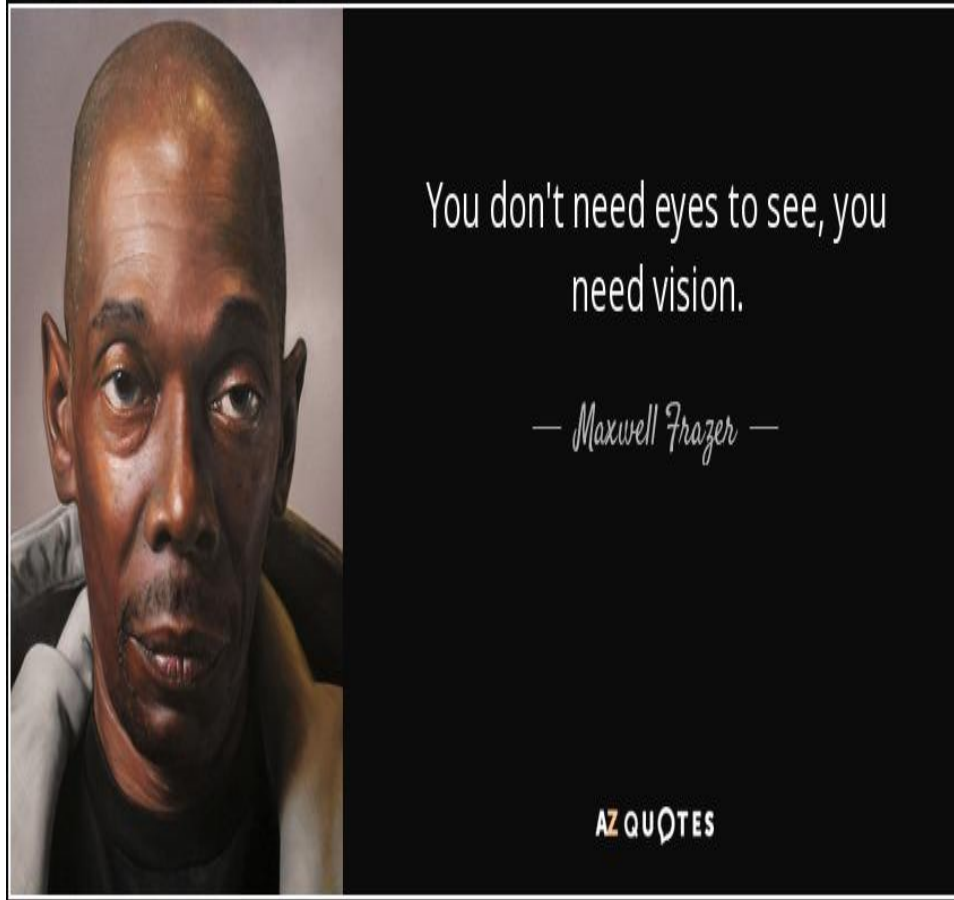
CAITLIN ROPER SCIENCE 02.18.14 1:30 PM

## THIS WOMAN INVENTED A WAY TO RUN 30 LAB TESTS ON ONLY ONE DROP OF BLOOD



Cleveland Clinic partners with Innovations winner  
Theranos for lab tests

# Thank You and any Questions?



- **John O Loughlin,**
- **Dept of Laboratory Medicine,**
- **Rotunda Hospital,**
- **Dublin 1,**
- **[joloughlin@rotunda.ie](mailto:joloughlin@rotunda.ie)**