



# THE RISK CONTINUUM

## SUSTAINABILITY FORUM

Joseph Thompson | Hamburg | 10 October 2019



IMPERIAL  
BRANDS

SCIENCE

# TO BUILD TRUST A PRODUCT MUST FIRST HAVE AN ACCEPTABLE SAFETY PROFILE. AND REDUCE RISKS RELATIVE TO SMOKING



IMPERIAL  
BRANDS

SCIENCE



Public Health  
England

“e-cigarettes are 95% safer than tobacco, but fewer than half of smokers are aware of this fact”



Centers for Disease Control and Prevention  
CDC 24/7: Saving Lives, Protecting People™

“Whilst investigations are ongoing we recommend that you consider refraining from using e-cigarette, or vaping, products, particularly those containing THC”

- What’s the safety profile of the product? (Absolute risk)
- Is it substantially reduced risk relative to combustible cigarettes? (Relative risk)
- What are the risks and benefits to the population as a whole?

# PRODUCT SAFETY & STANDARDS IS THE FIRST PRIORITY



IMPERIAL  
BRANDS

SCIENCE

## Safety Assessment

### Product Standards

- Quality of ingredients, materials, and component parts
- Full product characterisation
- Standardised product safety tests
- Standardised laboratory methods
- Robust risk assessment of final product by qualified professionals

### Quality Control

- In design
- In manufacture
- Batch release
- Product testing
- Microbiological testing
- Stability testing

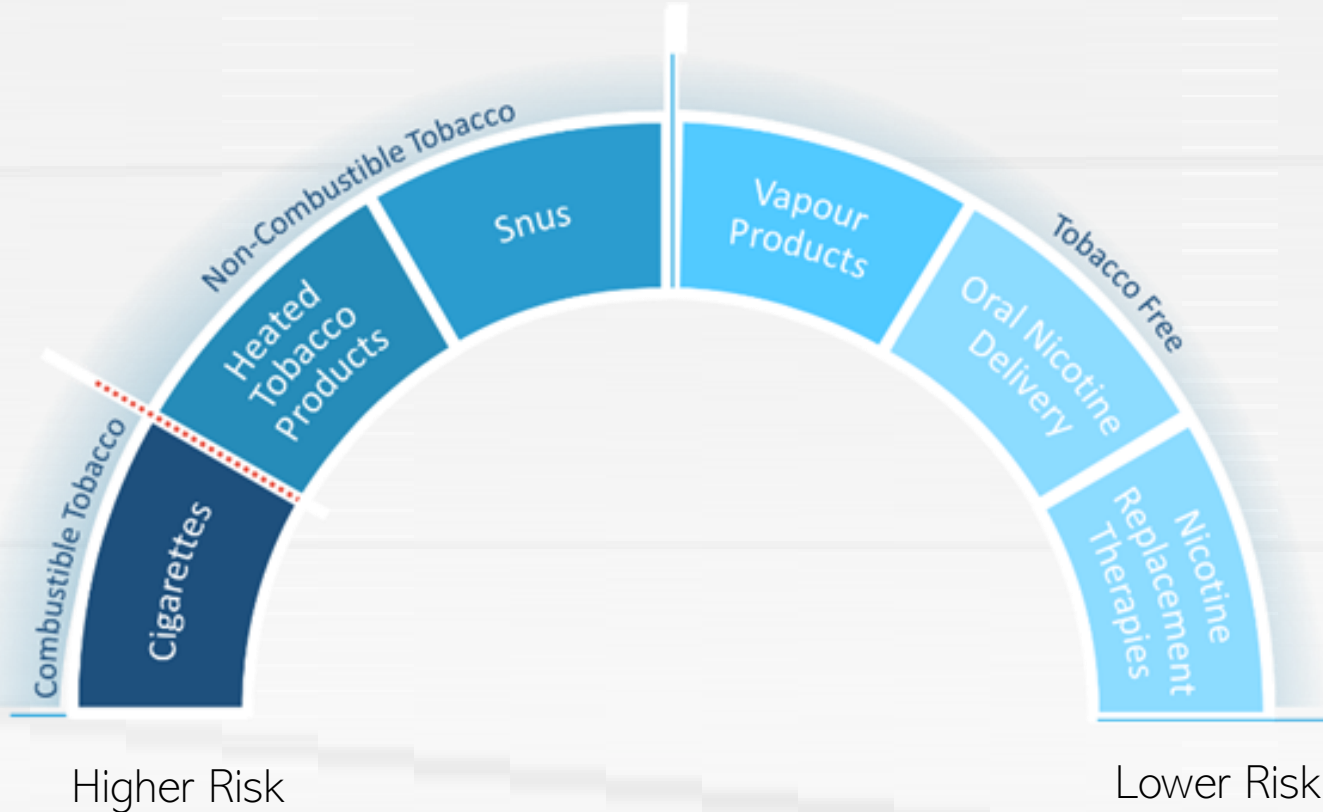
### Regulatory Compliance

- General Safety regulations
- Tobacco Product regulations
- Device specific regulations
- Packaging & Labelling regulations

### Mitigating Product Safety Risks

- What's the absolute risk profile of the product?
- Modification required?
- Warning required?
- Other mitigating actions? (e.g. responsible marketing)

# ROBUSTLY TESTED PRODUCTS MUST BE DEMONSTRATED TO BE REDUCED RISK RELATIVE TO COMBUSTIBLE CIGARETTES

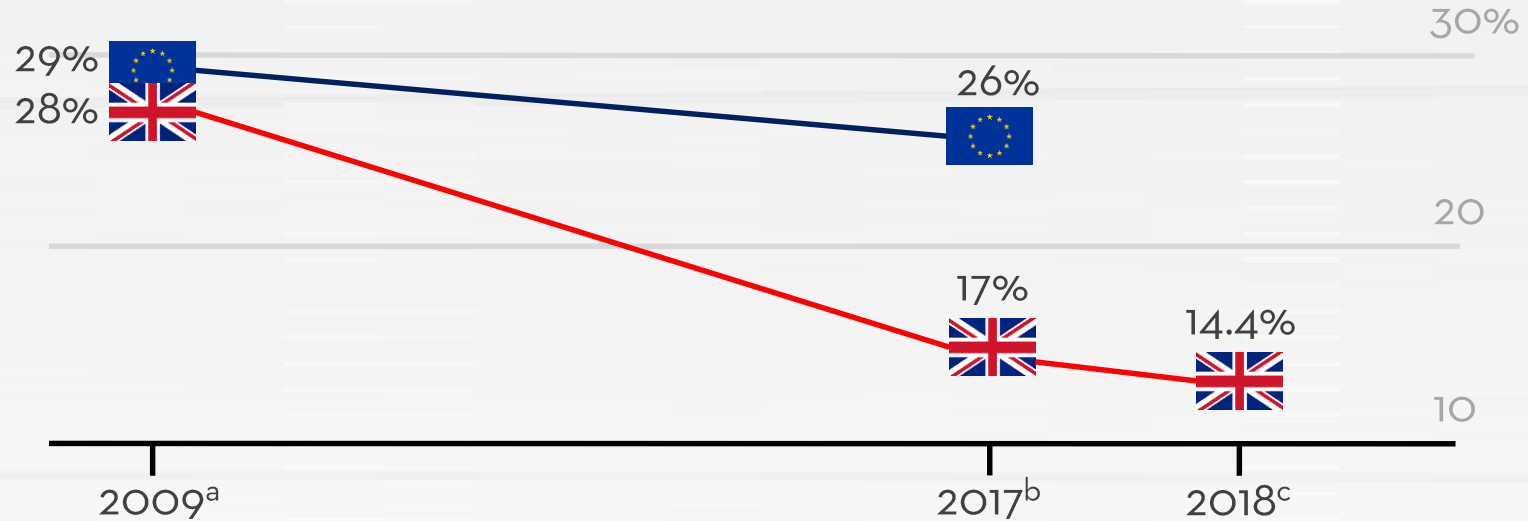


# THE POTENTIAL BENEFITS TO THE POPULATION ARE SUBSTANTIAL



IMPERIAL  
BRANDS

SCIENCE



a Special Eurobarometer 332 (2009)

b Special Eurobarometer 458 (2017)

c UK Office for National Statistics (2019)

# ASSESSING THE RISKS & BENEFITS MUST INCLUDE THE PRODUCTS POTENTIAL, WHETHER IT WILL BE USED BY ADULT SMOKERS, AND ANY UNINTENDED CONSEQUENCES



IMPERIAL  
BRANDS

SCIENCE

$$\begin{aligned} \text{Population Harm Reduction} &= \text{Reduced Risk Potential} \times \text{Consumer Acceptance} \\ \text{Consumer Acceptance} &= \text{Product Appeal to current adult smokers} + \text{Sustained Product Use by current adult smokers} \end{aligned}$$

$$\begin{aligned} \text{Unintended Use by youth and never smokers} &= \text{Consumer Acceptance} = \text{Product Appeal to current adult smokers} + \text{Sustained Product Use by current adult smokers} - \text{Unintended Use by youth and never smokers} \end{aligned}$$

# THE *SIMPLIFIED* HARM REDUCTION EQUATION



IMPERIAL  
BRANDS

SCIENCE

Population Harm Reduction = Reduced Risk Potential X

Product Appeal

to current adult smokers

+ Sustained Product Use

by current adult smokers

- Unintended Use

by youth and never smokers

*"off-ramping"  
from smoking*

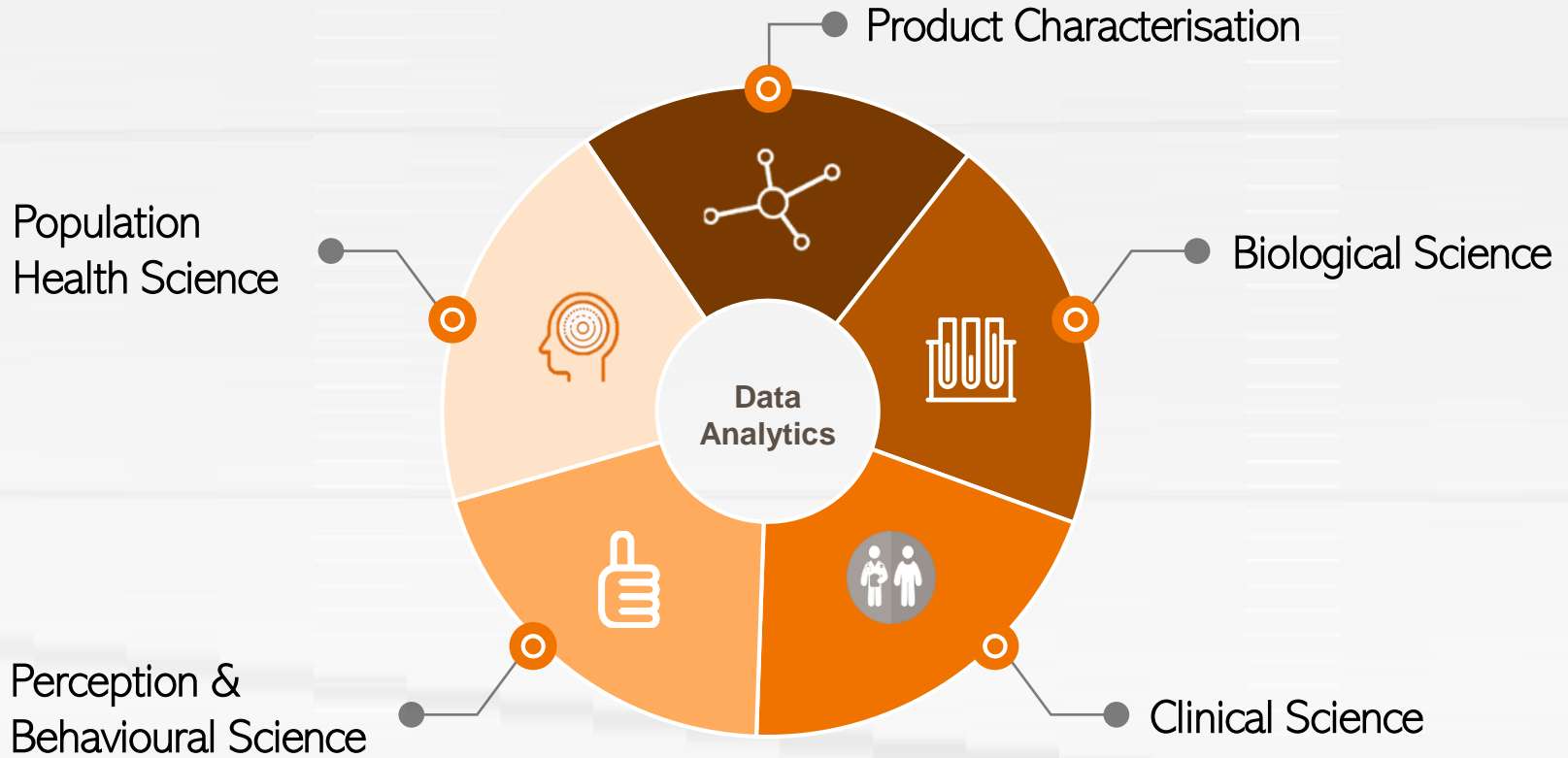
*"on-ramping"  
onto nicotine*

# REDUCED RISK POTENTIAL MUST BE CONTINUALLY ASSESSED THROUGH ROBUST FRAMEWORKS



IMPERIAL  
BRANDS

SCIENCE





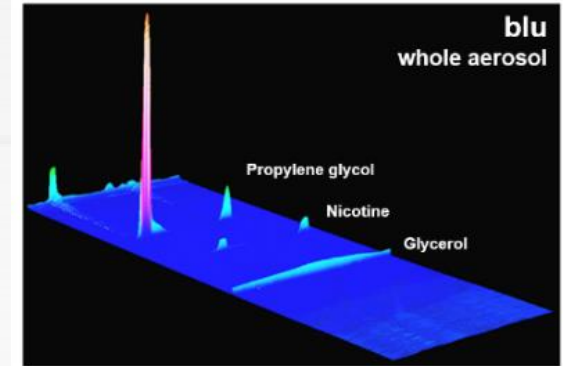
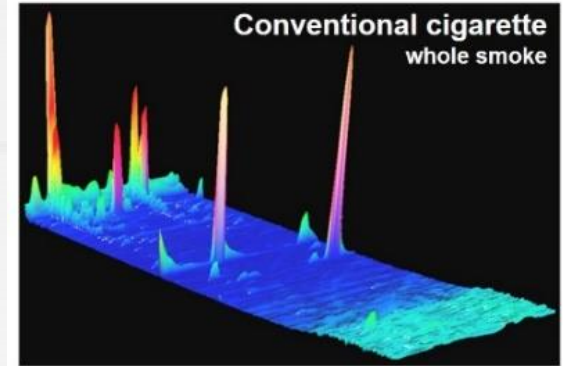
# IS THE PRODUCT WELL DESIGNED AND MANUFACTURED, AND DOES IT SUBSTANTIALLY REDUCE EXPOSURE TO HPHCS\*



IMPERIAL  
BRANDS

SCIENCE

Product Design & contents  
Product Use & Dosimetry  
Manufacturing Controls  
Product & Device safety cf. other consumer products  
HPHCs compared to cigs  
Particle size of any aerosol  
Stability testing  
Extractable & Leachables  
Untargeted screening

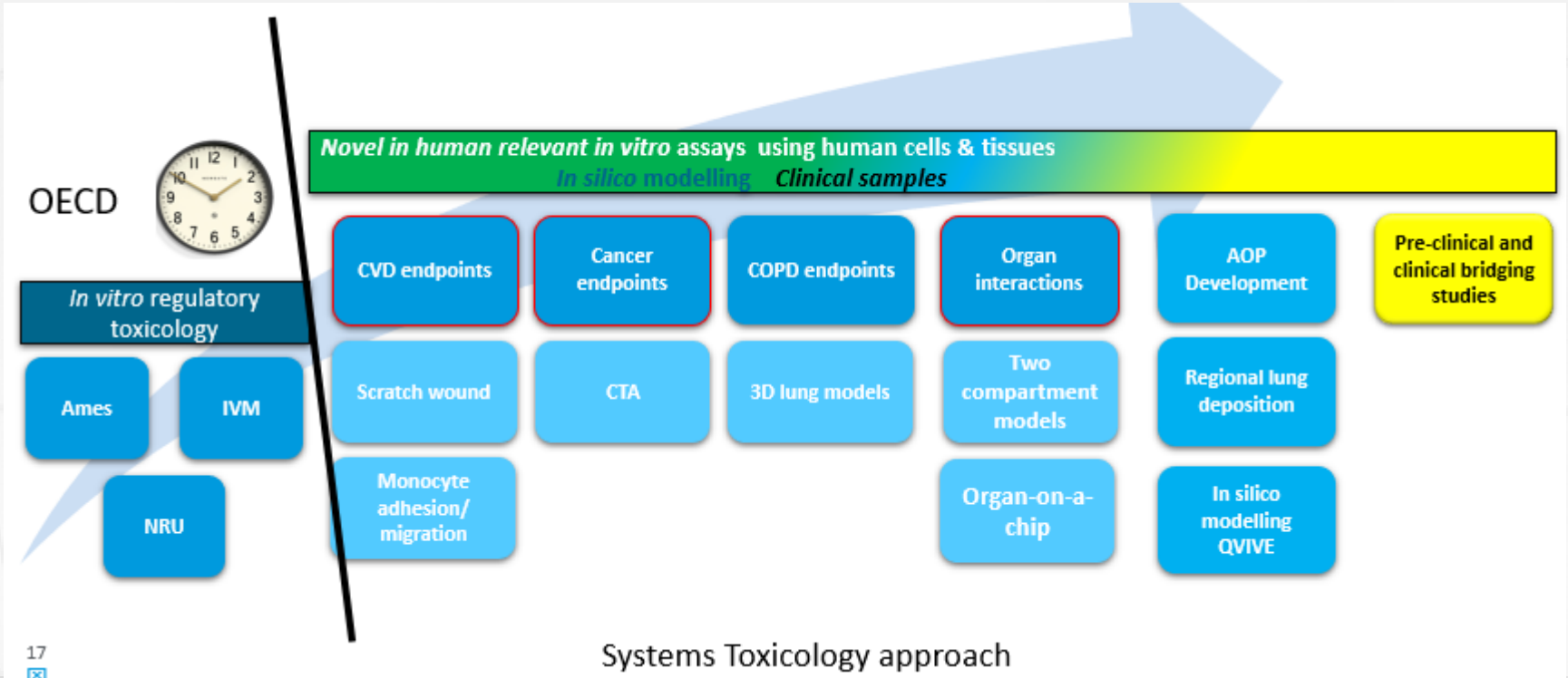


# DOES PRE-CLINICAL DATA SHOW THAT THE PRODUCT IS POTENTIALLY REDUCED RISK AND IS APPROPRIATE FOR CLINICAL STUDIES?



IMPERIAL  
BRANDS

SCIENCE



# DOES YOUR CLINICAL DATA SUBSTANTIATE REDUCED RISK POTENTIAL AND DEMONSTRATE IT'S RELATIVE SAFETY AND EFFICACY

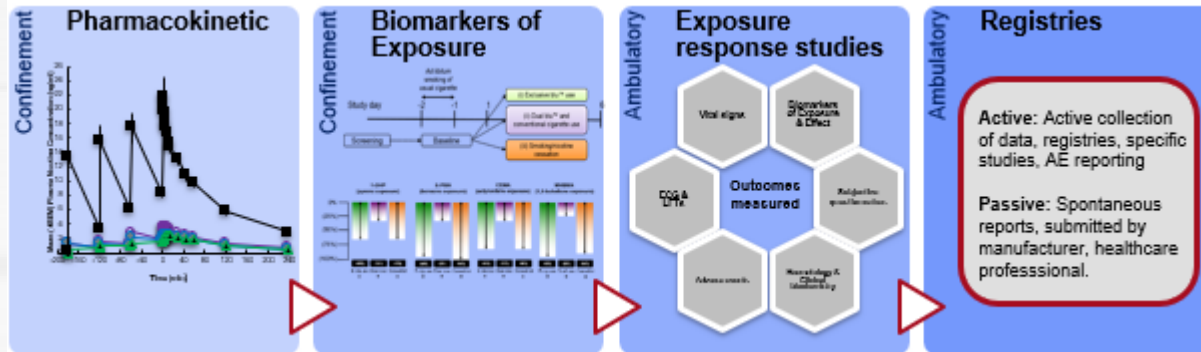


IMPERIAL  
BRANDS

SCIENCE

Pharmacokinetics of nicotine delivery  
Pharmacodynamics of nicotine delivery  
Reduction in biomarker or exposure  
Reduction in biomarkers of harm

Lung function & health  
Cardiovascular effects  
Safety & Tolerability (inc. Adverse Events)  
Combustible cigarette use



# IS THE IMPACT ON THE ENVIRONMENT ACCEPTABLE?



IMPERIAL  
BRANDS

SCIENCE

Indoor Air Quality

Exposure to by-standers

Land Use

Emissions to air and water feeds

Waste disposal from manufacturing

Recycling Schemes

Landfill

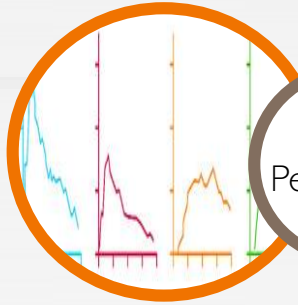


# DO YOU UNDERSTAND HOW THE PRODUCT IS USED?



IMPERIAL  
BRANDS

SCIENCE



Risk  
Perception



Use  
Behaviour



Intentions  
to Use



Comprehension  
& Labelling



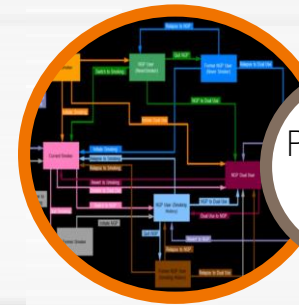
Cross  
Sectional &  
Cohort



Product  
Misuses



Safety  
Tracking



Population  
Models

# DO YOU HAVE THE SYSTEMS IN PLACE TO CONTINUALLY ASSESS THE SAFETY OF THE PRODUCT, AND RESPOND?



IMPERIAL  
BRANDS

SCIENCE



Evaluate scientific & medical literature



Assess consumer health complaints



Monitor notifications to regulators



Studies to assess benefit/impact on population



# SUMMARY

1. Robust product safety assessment first
2. Regulators must set product standards
3. Comprehensive programmes are required to assess reduced risk potential
4. Reduced risk potential is a continual assessment
5. Population benefits and risks is a holistic assessment