

A decorative dotted line of light blue circles starts in the upper left and curves downwards and to the right, ending near the bottom center of the slide.

**Innovation and harm reduction of alternative nicotine products: Balancing rapid product innovation with the need for robust product science**

Luca Rossi

VP Product and Process Technology

June 9, 2022

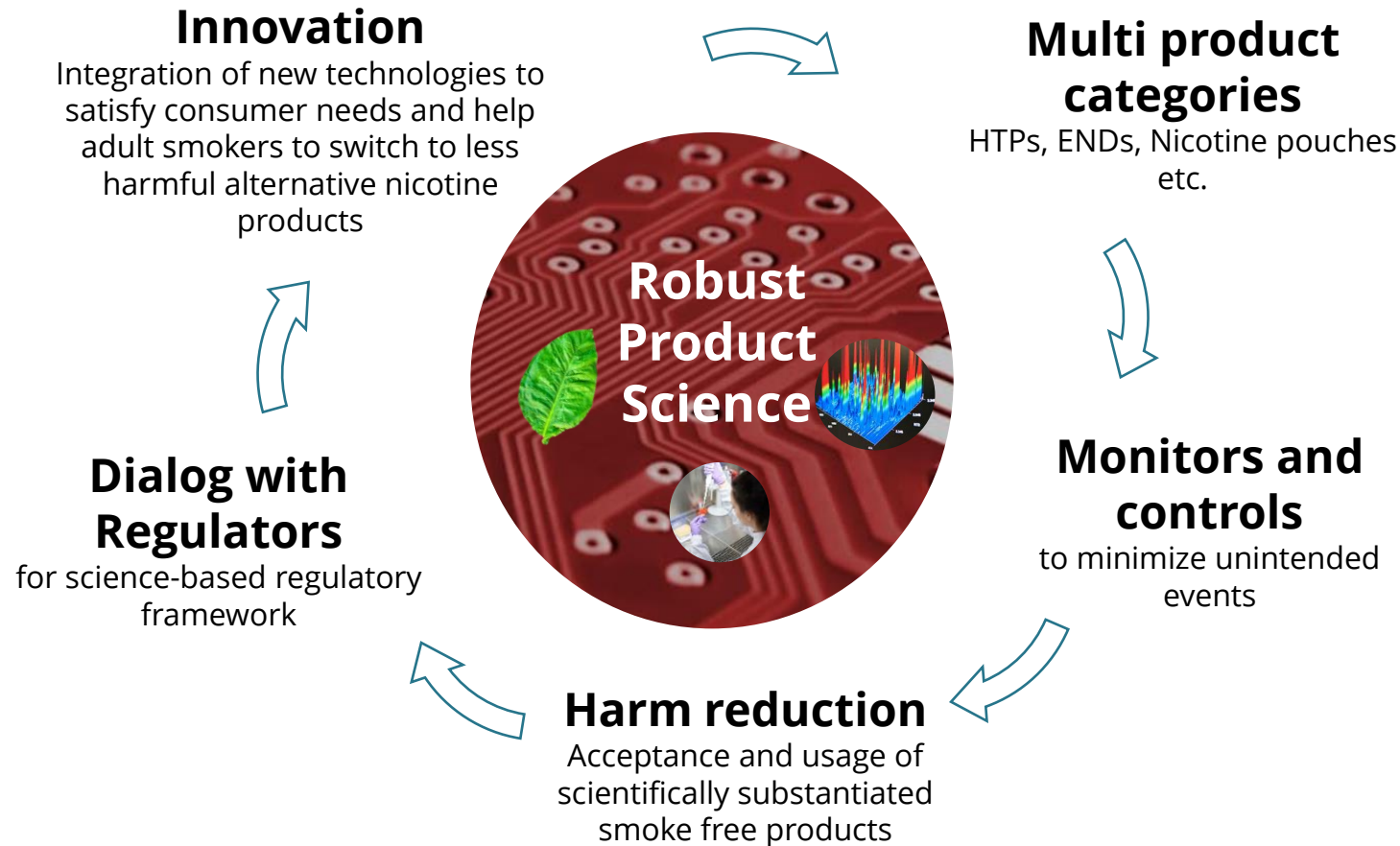


PMI SCIENCE  
PHILIP MORRIS INTERNATIONAL



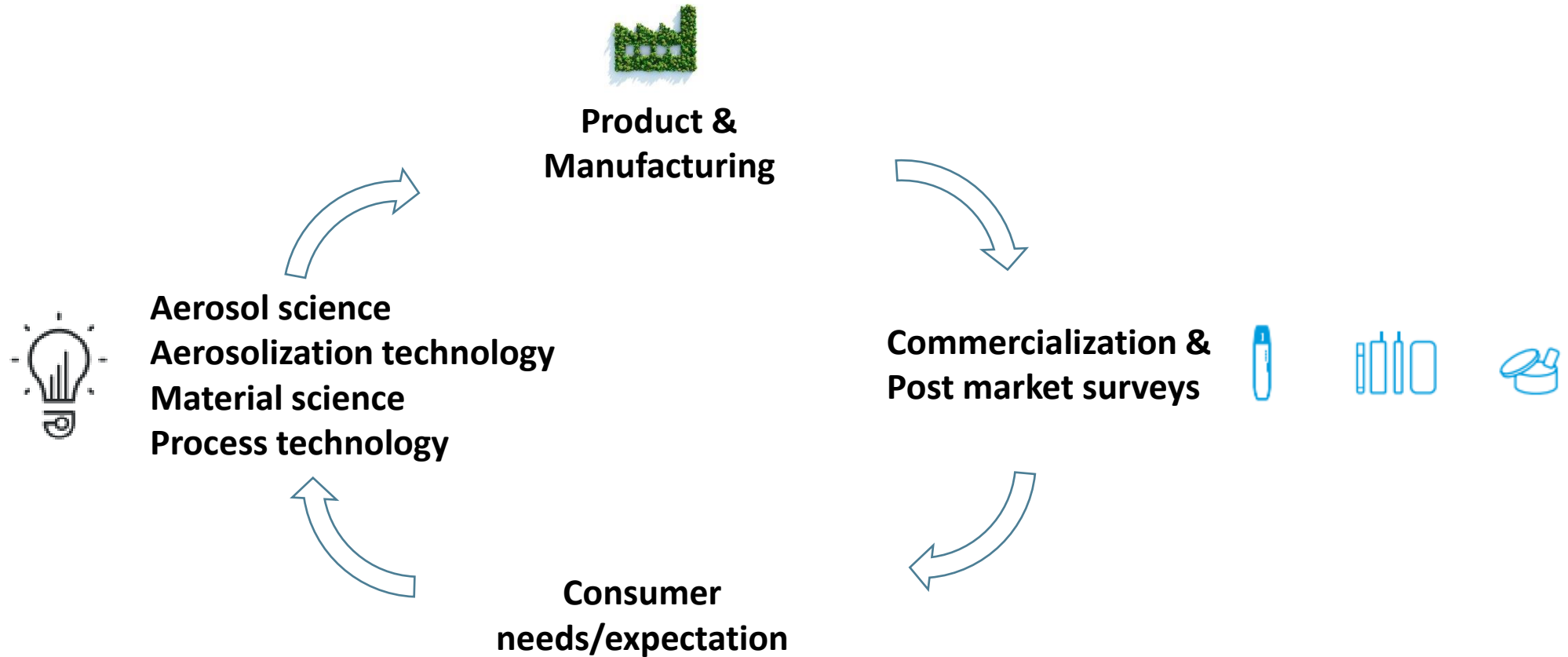
# Innovation and Tobacco Harm Reduction

Our main goal is to design a smoke-free future and provide a portfolio of product options helping adult smokers, who otherwise continue to smoke, to switch to less harmful alternative nicotine products





# Innovation Cycle



**Innovation cycle becomes shorter for smoke free products and product science play key role on speed to market**



# Pillars of Robust product science

## Product Design and Control Principles

- Product design using QbD principles
- Manufactured to appropriate quality standards and is sufficiently characterized to document product performance parameters.
- All components and ingredients of both consumables and devices are appropriate for use and will not present new or increased toxicity
- Controls in place to minimize unintended events
- No combustion is occurring during the use of the product
- There is a reduction of the levels of HPHCs in comparison to cigarettes
- Reduced toxicity in *in vitro* systems in comparison to cigarettes

## Chemical and Physical Characterization

## Non-clinical Toxicology and Risk Assessment

## Clinical studies

- Pharmacokinetic studies do not raise additional questions for nicotine uptake
- Reduced formation of HPHCs leads to reduced exposure in humans
- Reduced risk and harm

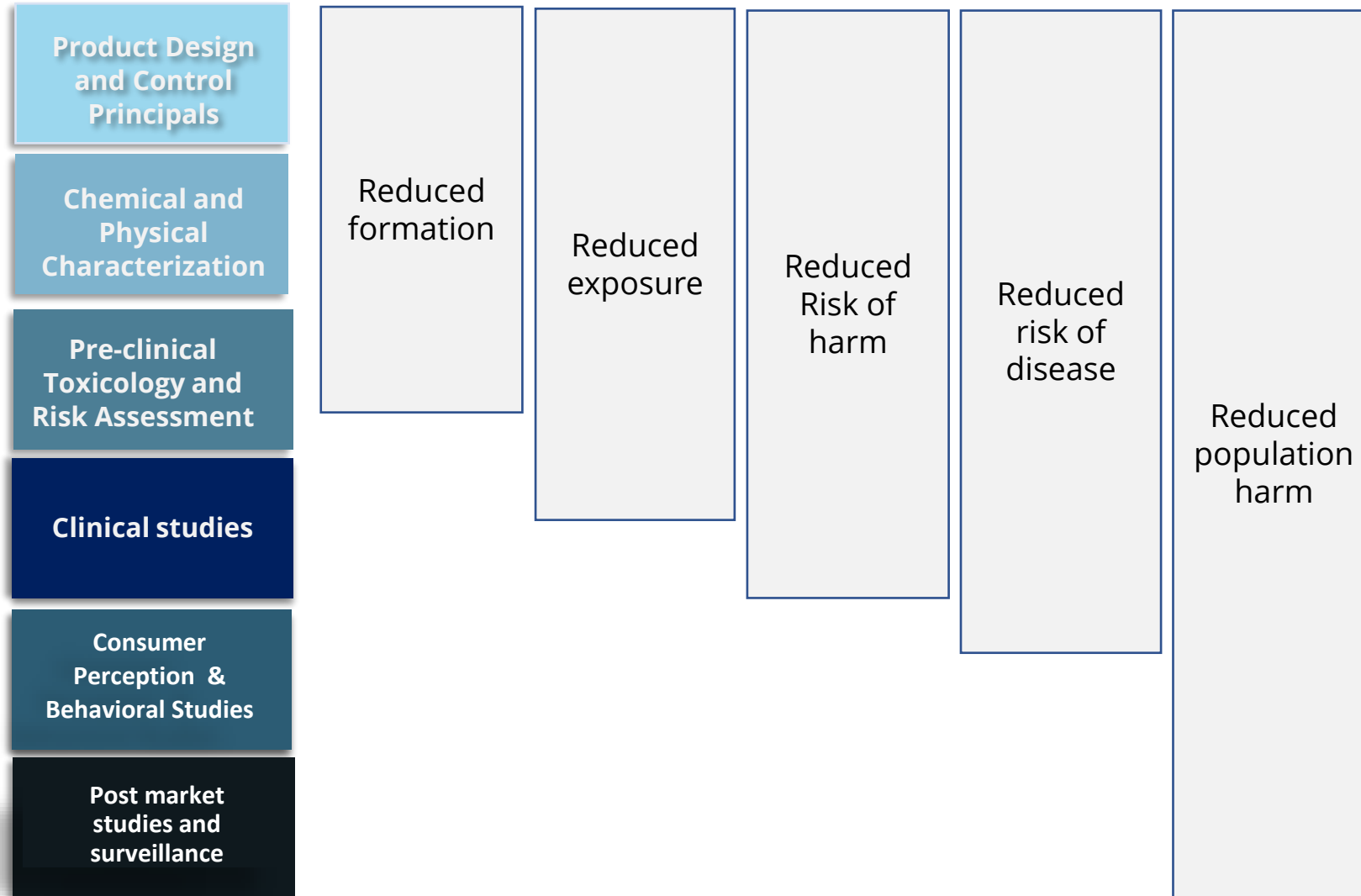
## Consumer Perception & Behavioral Studies

- Product use behavior among adult smokers and non-smokers
- Product design and messaging is such that is appropriate for adult smokers but not attractive to youth and non-smokers

## Post market studies and surveillance

- Consumer perception tobacco use behavior
- Longer-term assessment of exposure and health outcomes
- Adverse events related to product use

# Right balance between speed of innovation and robust product science



Common best practices and standards that govern minimum product design and performance can bring consistency and predictability in a regulated environment and facilitate engagement with regulators for science-based regulatory framework



# Summary

- Our main goal is to design a smoke-free future and provide a portfolio of product options helping adult smokers who otherwise continue to smoke switch to less harmful alternative nicotine products
- Rapid innovation is the key to develop smoke free products, integrating consumer needs into the latest technologies
- Robust product science is core to developing and assessing those products and demonstrate their harm reduction potential
- Common best practices and standards that govern minimum product design and performance, bring consistency and predictability in a regulated environment and can facilitate engagement with regulators for science-based regulatory framework

**THANK YOU FOR YOUR ATTENTION.**