

# Heated Tobacco Products: Regulatory Science

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May 6<sup>th</sup> 2016

# Important Information

*Reduced-Risk Products (“RRPs”) is the term PMI uses to refer to products with the potential to reduce individual risk and population harm in comparison to smoking cigarettes.*

*PMI’s RRP’s are in various stages of development and commercialization outside the United States in a number of countries, and we are conducting extensive and rigorous scientific studies to determine whether we can support claims for such products of reduced exposure to harmful and potentially harmful constituents in smoke, and ultimately claims of reduced disease risk, when compared to smoking cigarettes.*

*Before making any such claims, we will rigorously evaluate the full set of data from the relevant scientific studies to determine whether they substantiate reduced exposure or risk.*

*Any such claims may also be subject to government review and authorization, as is the case in the United States today.*



# The Objective is Individual and Population Benefit



...the primary problem is combustion,  
not nicotine

# The Objective is Individual and Population Benefit

## Heated Tobacco Products

Platform 1  
iQOS\*



Platform 2



## Nicotine-Containing Products

Platform 3



Platform 4

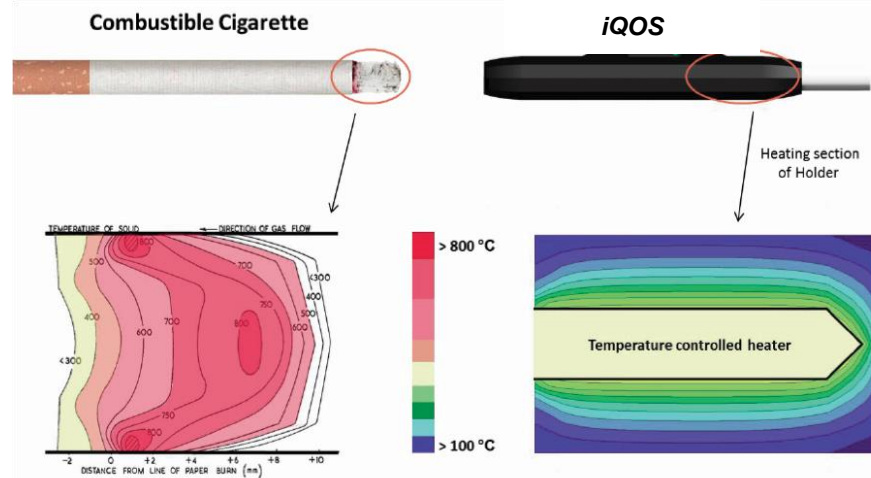


# Heating Tobacco Rather than Burning it is a Promising Opportunity



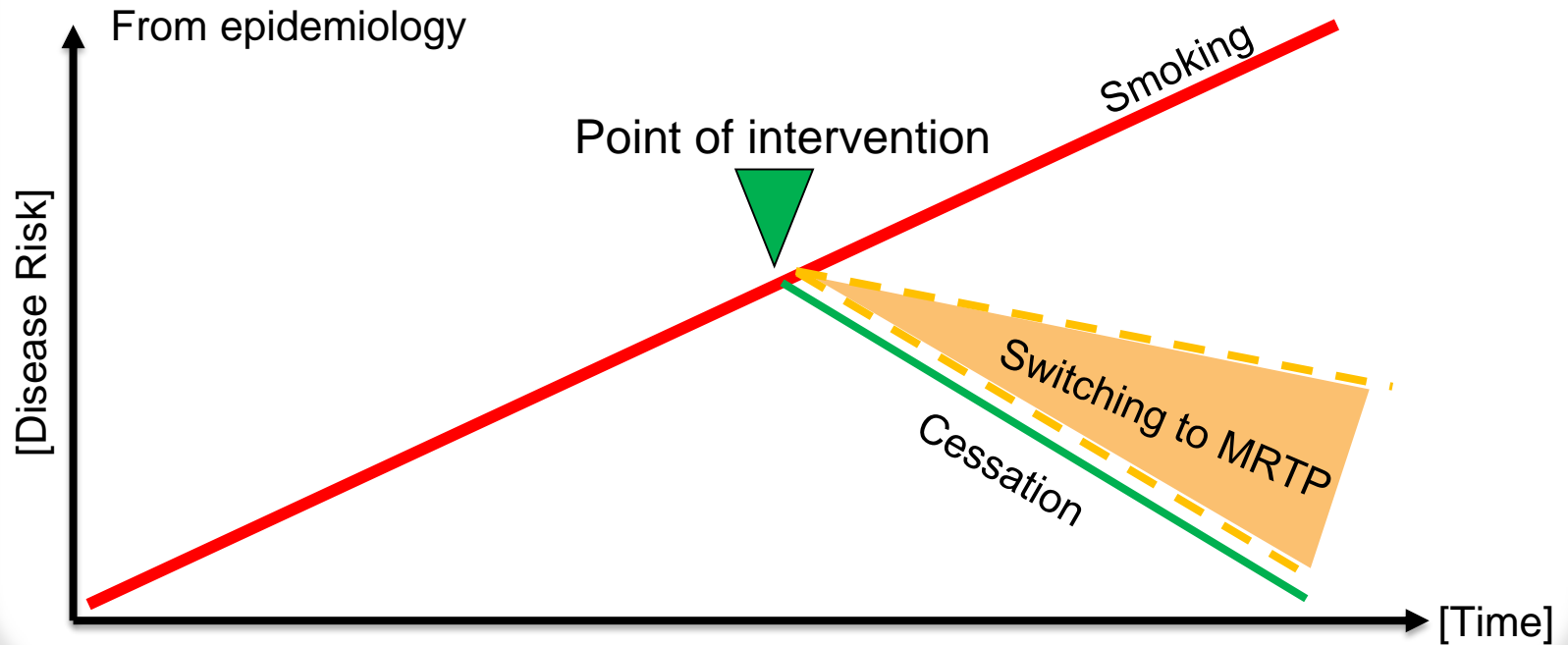
Designed to:

- Significantly reduce or eliminate the formation of harmful or potentially harmful compounds
- Preserve elements of the taste, sensory experience, nicotine delivery profile and ritual characteristics of cigarettes



# Demonstrating Reduced Harm / Risk

Using Smoking Cessation as a Benchmark



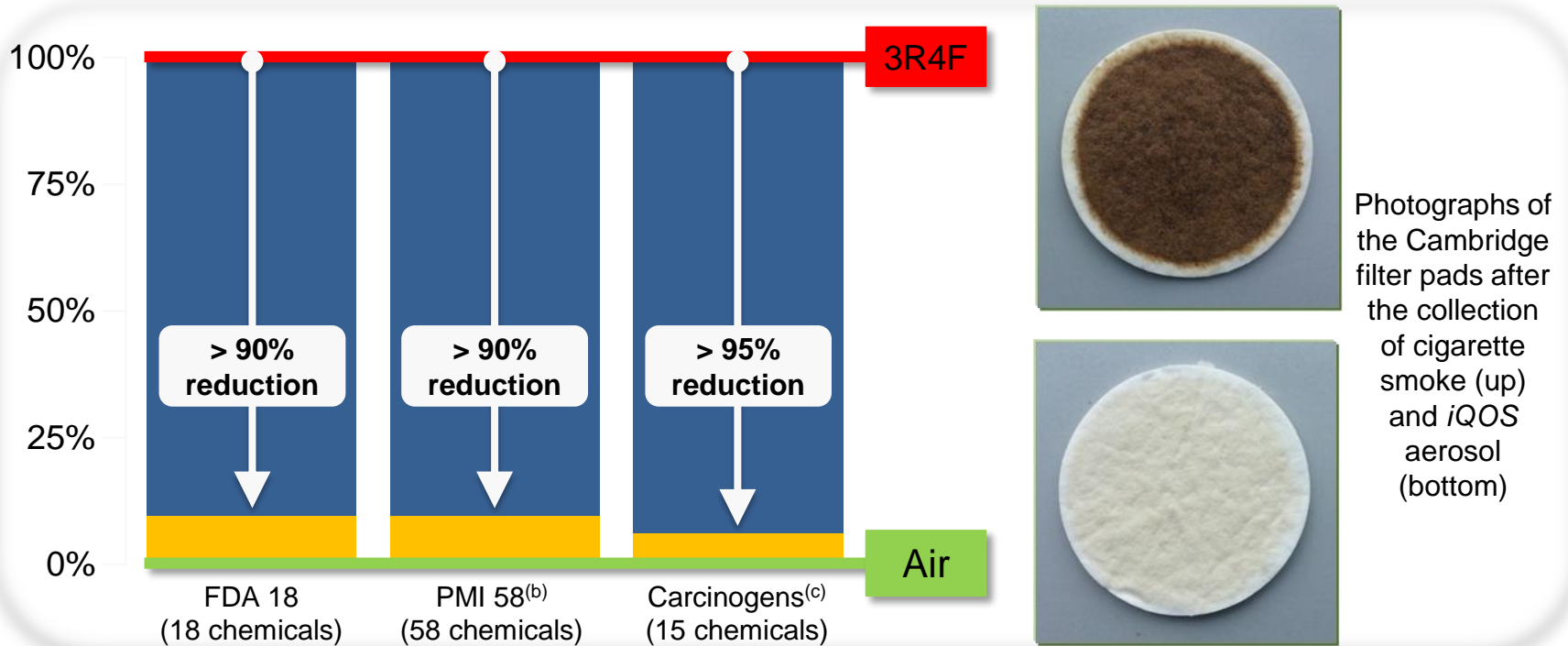
For Illustration Purposes Only

# PMI's Evidence-Based Assessment Approach



# Laboratory Studies Demonstrate Reduced Formation

Average reductions in the formation of harmful or potentially harmful compounds for iQOS compared to levels measured in smoke from the 3R4F reference cigarette<sup>(a)</sup>



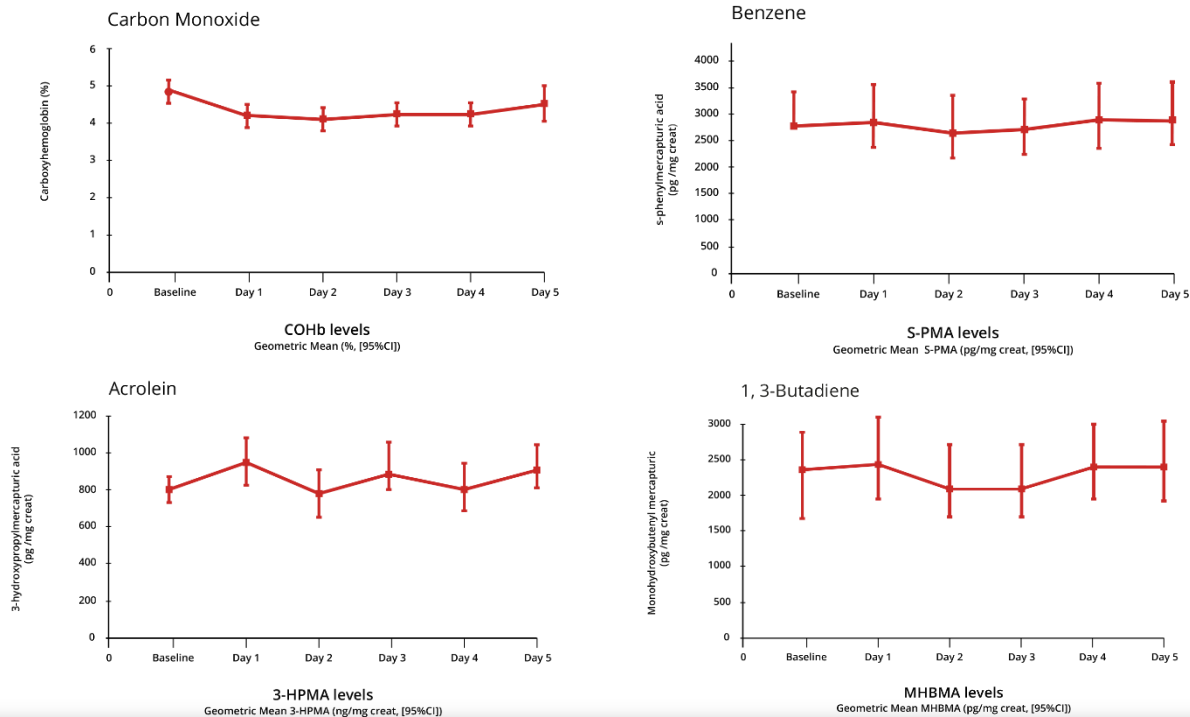


# Clinical Studies in Smokers Demonstrate Reduced Exposure

**Adult smokers used the products *ad libitum***

Adult smokers randomized to cigarettes or *iQOS* were free to use the product as often as they wished

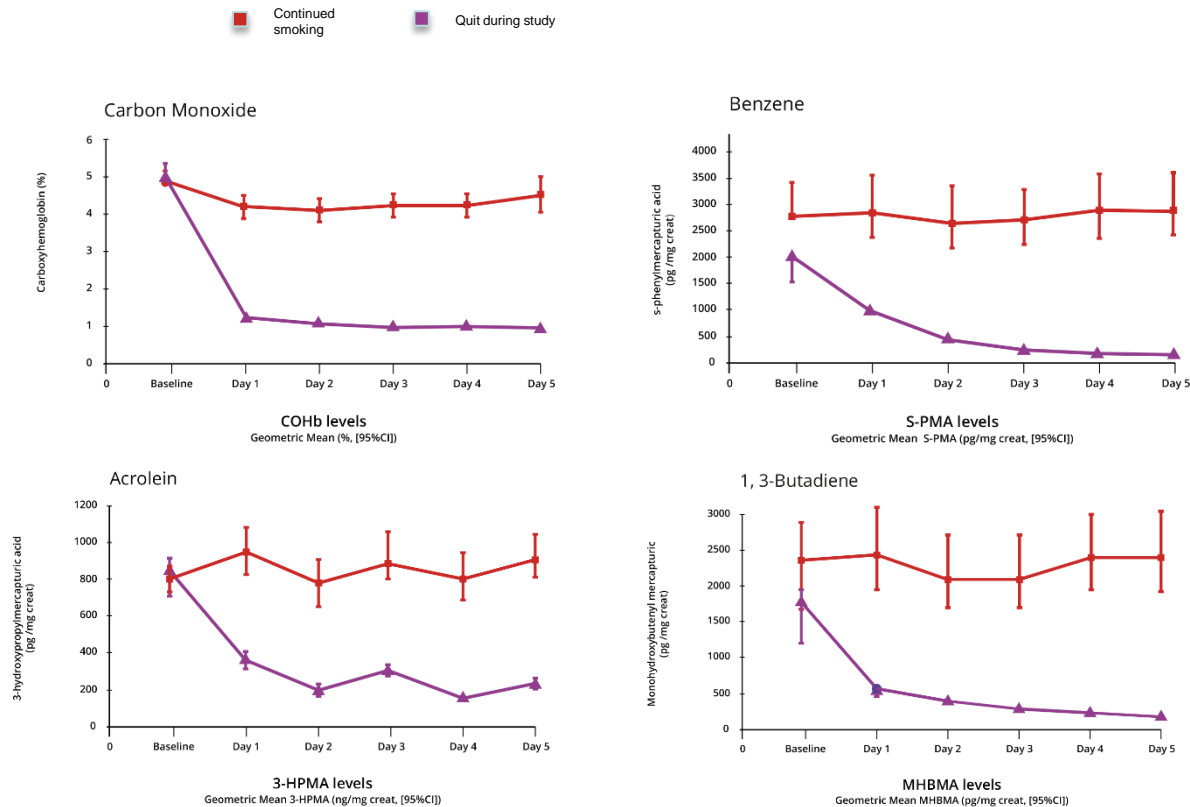
Continued Smoking



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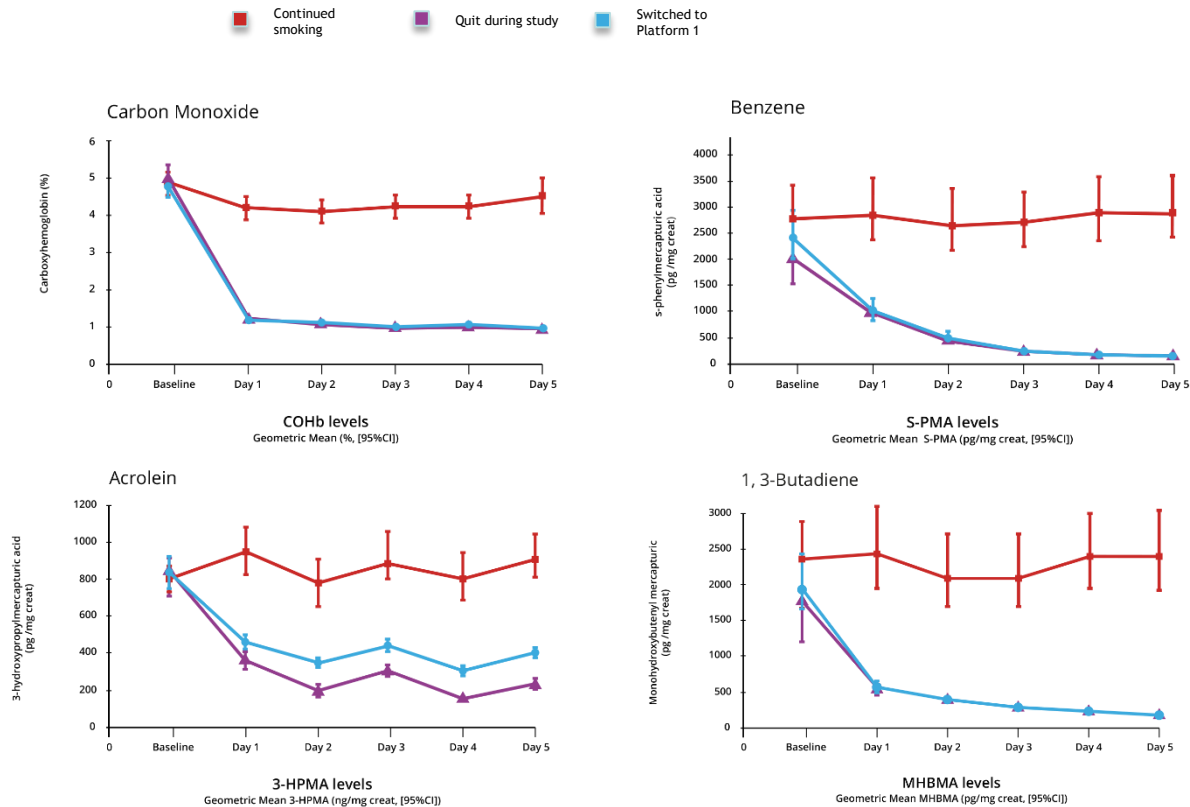
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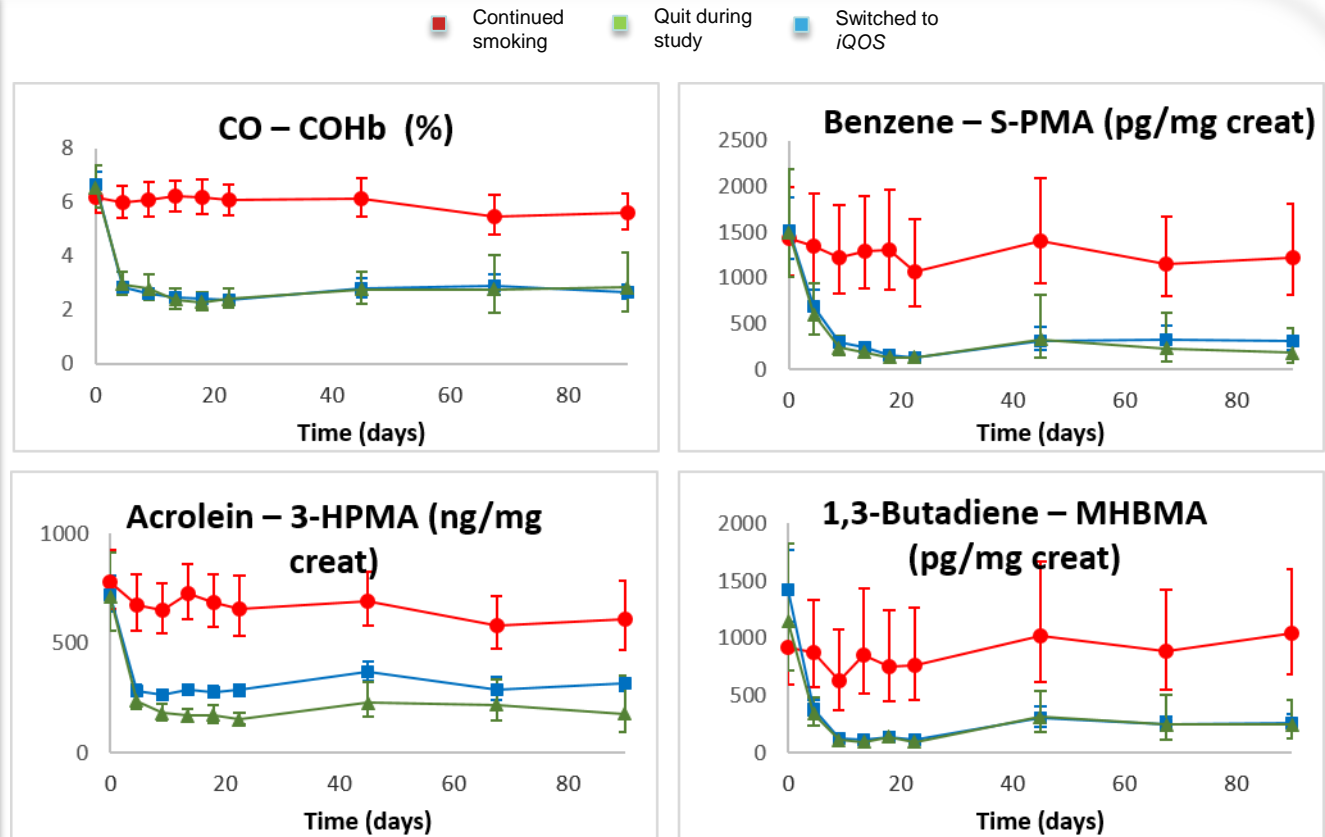
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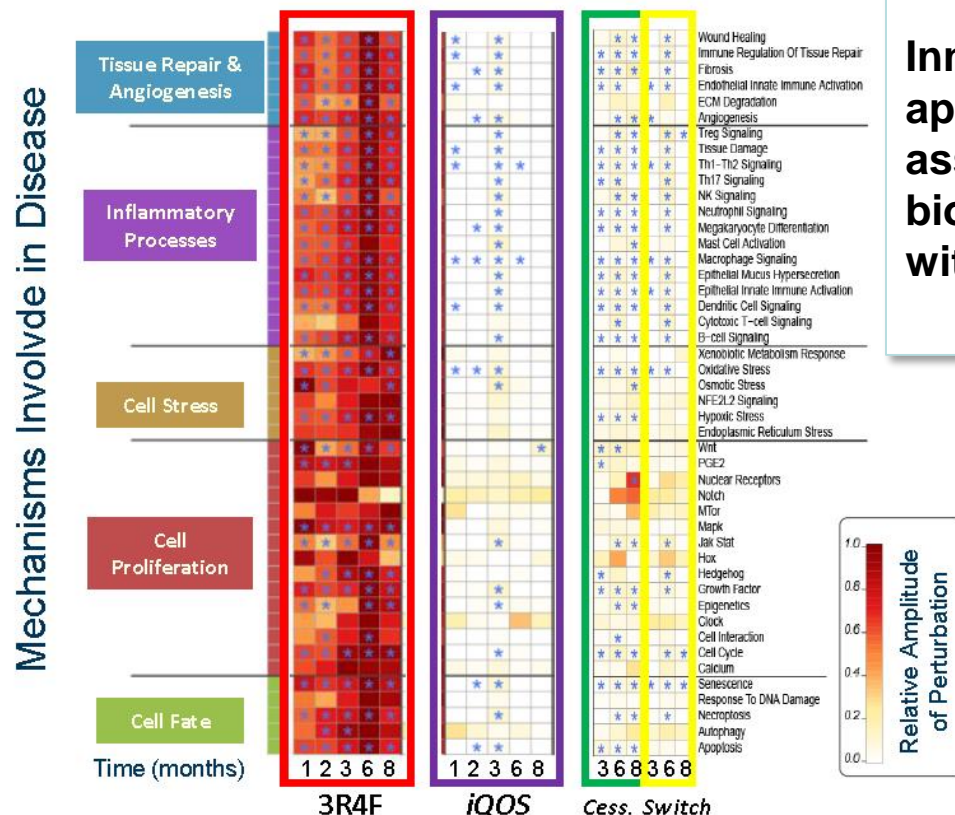
# Clinical Studies in Smokers Demonstrate Reduced Exposure

## Adult smokers used the products *ad libitum*

Adult smokers randomized to cigarettes or *iQOS* were free to use the product as often as they wished, in confinement (5 days) and then ambulatory (85 days)



# Demonstrating Reduced Disease Risk: Non-Clinical and Clinical Studies



**Innovative Systems Toxicology approaches have been used to assesses the impact of *iQOS* on biological mechanisms associated with disease.**

**Clinical program is on-going. Markers known to be associated with smoking-related diseases are being measured over different timeframes up to 12 months in duration**

ClinicalTrials.gov Identifiers:  
NCT01970995, NCT01970995, NCT02396381

# Where We Are

- Heating tobacco, instead of burning it, has the potential to reduce exposure to harmful or potentially harmful compounds
- *iQOS*, our most advanced heated tobacco product, was launched in Nagoya in 2014 and the post market surveillance data is encouraging:
  - Over 100,000 adult smokers have already quit smoking and have converted to *iQOS* exclusively
  - Interest among never-smokers and former smokers is negligible, while adult smokers have demonstrated high interest in the product – this is consistent with pre-market perception and behavior studies, including those conducted in the United States
- Ability of FDA to deal rapidly with innovation in order to enable informed consumer choice is of critical importance