**POSTER 135/GFN 2017:** J. MURPHY
A framework for assessing the reduced risk potential of e-cigarettes at individual and population levels
**Global Forum on Nicotine** | Warsaw, Poland, June 2017

NEXT GENERATION PRODUCTS

BRITISH AMERICAN TOBACCO

# A framework for assessing the reduced risk potential of e-cigarettes at individual and population levels

Novel tobacco products with reduced yields of toxicants compared to cigarettes, such as tobacco-heating products, snus and electronic cigarettes, hold great potential for reducing the harms associated with tobacco use.
The US FDA, has provided draft guidance outlining a framework to assess novel products as Modified Risk Tobacco Products (MRTP). Based on this, we have proposed a framework comprising three key assessment phases: pre-clinical, clinical, and population studies. This integrated approach proposes the use of these studies to assess the risk reduction potential of novel tobacco and nicotine products at the individual and population levels (Fig 1).

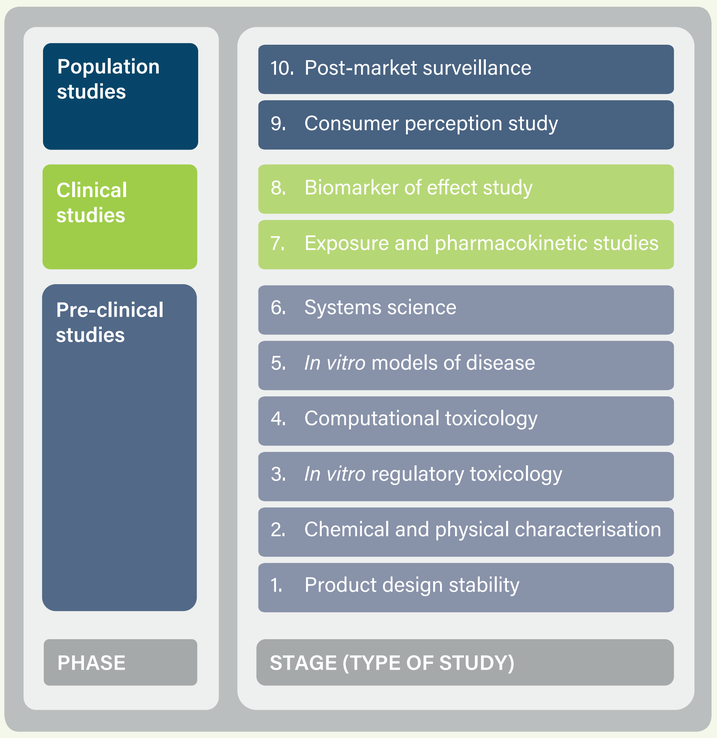
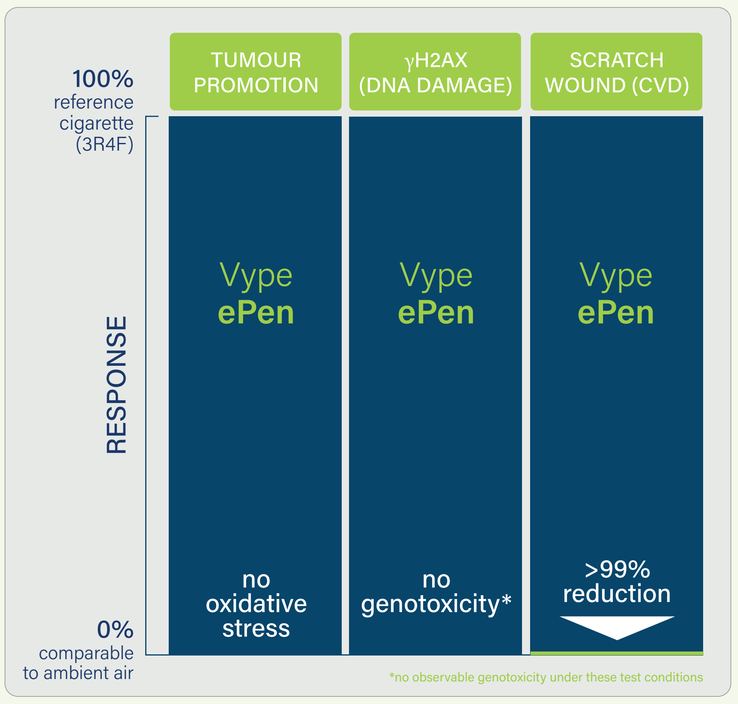



**Figure 1 |** Scientific Framework for assessing the risk profile of NGPs.

**Figure 2a |** Lab based disease modelling toxicological tests comparing EC aerosol to 3R4F smoke.




## RESULTS AND DISCUSSION

The utility of the assessment framework was piloted by comparing EC (Vype ePen) against both reference and conventional cigarettes in a range of chemical, *in silico*, *in vitro* biological and human studies. The results form one of the most comprehensive datasets on a single e-cigarette to date and when considered in their totality are in line with the findings of Public Health England, that EC has the potential to be a reduced risk product in comparison to cigarettes.

For example, from the studies we observed that the aerosol from EC contains less toxicants in comparison to smoke from 3R4F.

This in turn drove fewer biological responses in a range of *in vitro* studies investigating classical regulatory endpoints, disease modelling and systems science (Figures 2a and 2b).

Longer term clinical studies and a range of pre- and post-market population studies are required to substantiate EC as a product that can reduce risk on a population level.

The proposed framework would generate large and heterogeneous foundational datasets on an original 'reference' product. These datasets could be compared with similar data generated on other NGPs such as THPs, enabling the ranking of products across the risk continuum.

Additionally, in the fast paced world of NGP innovation, datasets could be transferred from the 'reference' NGP to 'similar' variants of that product, with data sets added on a needs basis.

An approach that meets the requirements of regulators, public health and manufacturers is required to ensure that the best possible NGPs, like e-cigarettes are being made available on the market, and that consumers are informed of their reduced risk potential in comparison to smoking cigarettes.

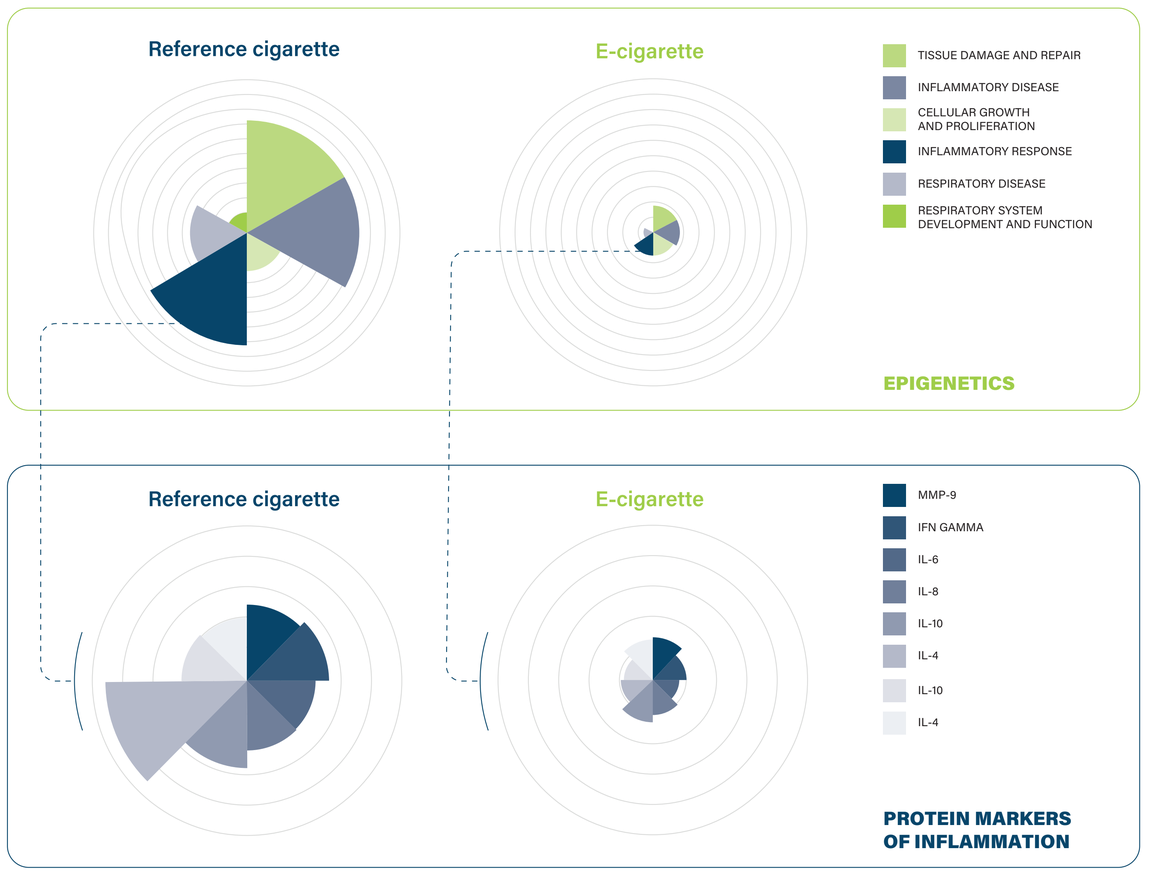



**Figure 2b |** Markers of disease and function after exposure to emissions from a reference cigarette and an e-cigarette. **EC promotes substantially less disease relevant gene responses in comparison to 3R4F.**

- A multi-disciplinary scientific framework is prosed for assessing the risk profile of Next Generation Products relative to cigarettes
- We have conducted a series of chemical, *in vitro* biological and a range of human studies on the Vype ePen, and compared it to a scientific reference cigarette
- The results from these studies, when considered in totality, are in line with the findings from Public Health England and the Royal College of Physicians and are an example of the potential of e-cigarettes to be reduced risk in comparison to cigarettes
- Longer term clinical studies will be required to confirm this potential to demonstrate risk reduction on a population level
- A bridging strategy is required that enables safety data to be transferred between similar product variants and ensure that better and more efficacious products are made rapidly available to smokers

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**James Murphy, Ian M Fearon, Oscar M Camacho, Marianna Gaça, Krishna Prasad, Bryony Kendall and Christopher Proctor**
james_murphy@bat.com | R&D, British American Tobacco, Southampton, SO15 8TL United Kingdom

@BAT_Sci