



HEATED TOBACCO

# Heated Tobacco and Heated Herbal Products Provide Adult Smokers with Satisfactory Nicotine Delivery: A Pharmacokinetic Study

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## Background



Tobacco  
Harm  
Reduction  
(THR)

Smoking is a cause of  
serious diseases in  
smokers, due to

**burning tobacco**

and inhaling smoke

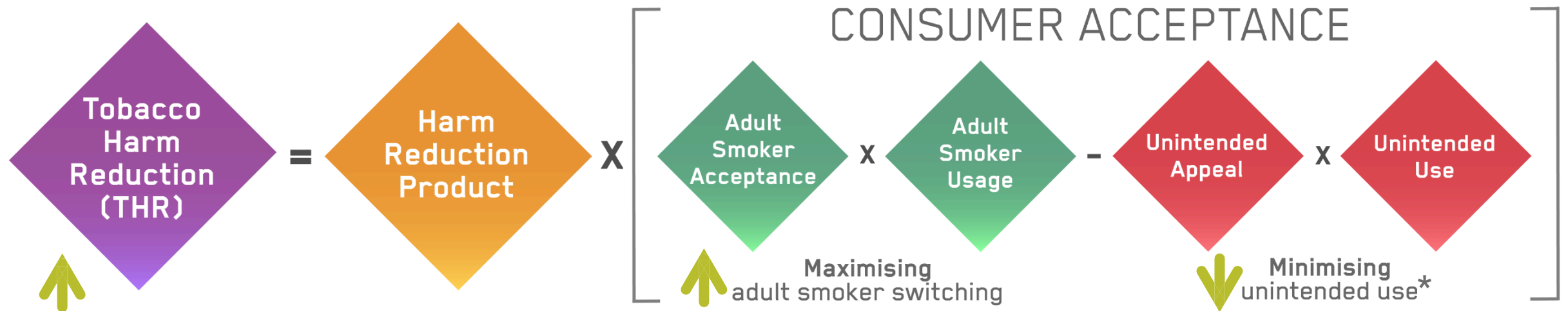
# Consumer Acceptance of NGP\* is Essential for THR

- THR refers to strategies designed to reduce the health risks associated with tobacco smoking



**THE HARM REDUCTION EQUATION:**  
HARM REDUCTION CAN ONLY WORK, IF NGP ARE POTENTIALLY LESS HARMFUL THAN SMOKING **AND** USED BY THE CONSUMER

# Effective THR Products Should Appeal to Adult Smokers but Importantly, not Unintended Populations



\*such as never smokers, ex-smokers or youth



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# Imperial Brands Scientific Assessment Framework (SAF)

Evaluating product safety and assessing the tobacco harm reduction potential of our NGP



Learn more about  
our SAF here:



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# Clinical Studies Provide Key Data to Assess the THR Potential of the NGP



## HOW?

**Pharmacokinetic (PK) and Pharmacodynamic (PD) studies** to evaluate how the body absorbs, distributes, and responds to nicotine



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**This study aimed to:**

- **Characterise the PK and PD profiles of PULZE 2.0 and iSENZIA/iD in comparison to cigarettes.**
- **Assess the acceptability of these products for current smokers and, as such, their potential as harm reduction alternatives to smoking.**



# Study Products



**PULZE 2.0 Heating System, that heats  
– but does not burn – either iD or  
iSENZIA consumables**



**iSENZIA:** Tea based substrate; 2.7mg nicotine per stick



**iD:** Reconstituted tobacco substrate; 4.6mg nicotine per stick

**Comparator:** Subject's Own Brand Cigarette



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# Study Overview for Assessing Nicotine Delivery in Novel Heated Products



## STUDY DESIGN

A randomised, open-label, crossover clinical trial to assess nicotine delivery of PULZE 2.0 heating system with iD and iSENZIA in comparison to cigarettes

## STUDY POPULATION



**Sample size**  
**n = 25**

Male & female healthy adult smokers

**Age**  
**21-65 years**

## STUDY PRODUCTS

HTP	Pulze 2.0 Device with iD Balanced Blue stick
HTP	Pulze 2.0 Device with iD Rich Bronze stick
HHP	Pulze 2.0 Device with iSENZIA Forest Berry stick
HHP	Pulze 2.0 Device with iSENZIA Summer Watermelon stick
Cigarette	Subject's Own Brand Cigarette (OBC)

Study Day -28

Subject Check-in

6 Day Confinement Period

Subject Discharge

Screening

Day -1/Product Familiarisation

1

2

3

4

5

Safety Follow-up Phone Call

7 Days Post Study

Study Day 1 through 5

Assigned 1 of 5 study product sequences  
PK samples and questionnaire administration

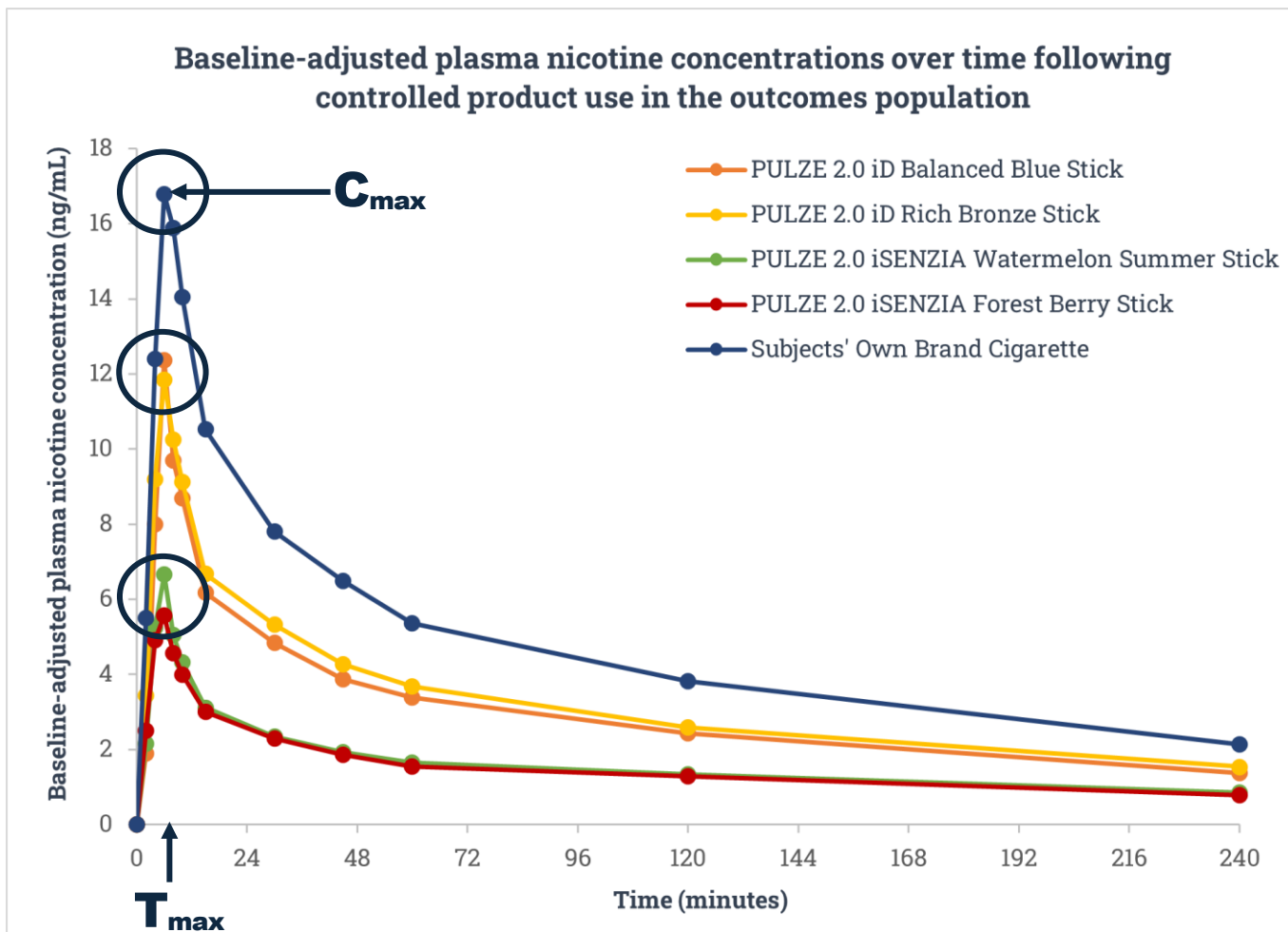


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# PULZE 2.0 and iSENZIA/iD Deliver Nicotine Efficiently with Reduced Abuse Liability Compared to Cigarettes



6 mins

$C_{\max}$  (ng/mL): maximum concentration of nicotine observed in the blood

$T_{\max}$  (min): time at which the  $C_{\max}$  of nicotine is reached in the blood



Heated products potentially have lower abuse liability compared to cigarette

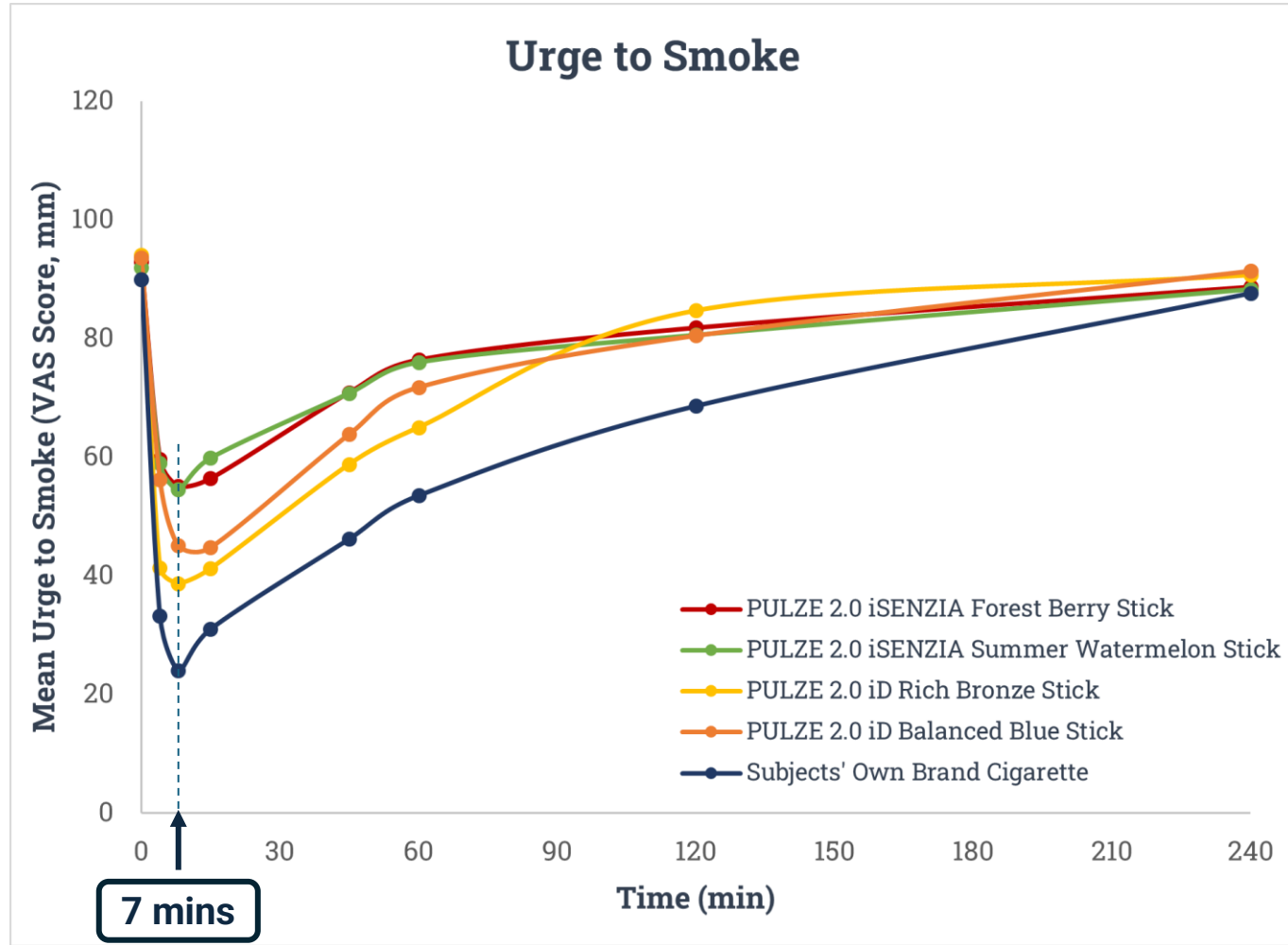


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# PULZE 2.0 and iSENZIA/iD Reduced the Urge to Smoke



Cigarette > iD > iSENZIA



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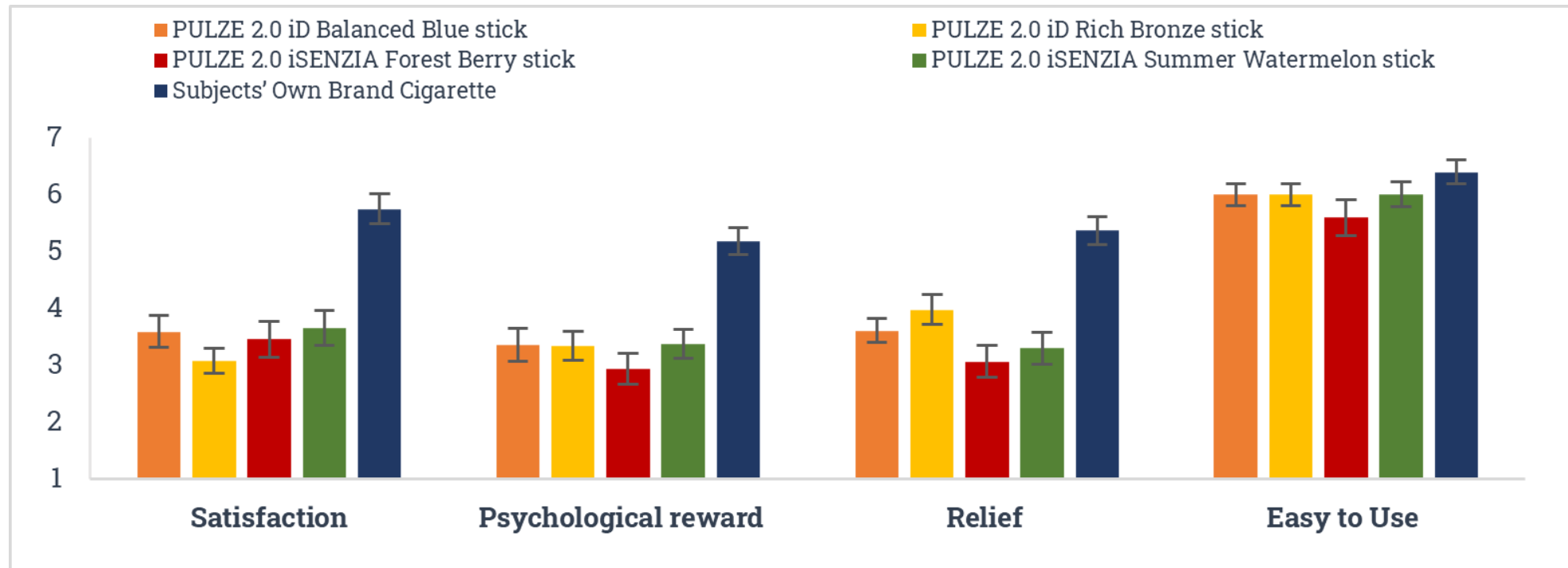
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# Results Indicate PULZE 2.0 Heated System\* Offers a Satisfying Alternative to Cigarettes for Adult Smokers



Product evaluation scores were comparable among heated products

36%-52% of subjects indicated they were likely to use PULZE 2.0 and iD/iSENZIA again



\*PULZE 2.0 device used in combination with iD or iSENZIA



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# Clinical Data Confirms Favourable Short-Term Safety Profile for the Assessed Heated Products



**No serious product-related adverse events** observed following the use of PULZE 2.0 and iD/iSENZIA sticks

**No significant changes** in blood pressure, pulse, heart measurements, or general wellbeing

PULZE 2.0 and iD/iSENZIA sticks were **tolerated by adult smokers** under study conditions

**All product-related adverse events** were **categorised as mild in severity** (e.g., dizziness, nausea and headache)



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# Conclusions



**Overall, PULZE 2.0 and iD/iSENZIA sticks could potentially be acceptable alternatives to cigarettes for adult smokers, while having potentially lower abuse liability compared to cigarettes**



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THANK YOU FOR YOUR ATTENTION!



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