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Actual Use Studies of blu\* ENDS demonstrates meaningful tobacco harm reduction potential: Secondary analysis of predictors of behaviour change

\*not available in the US but commercially available in multiple European countries.

## Disclaimer & Conflict of Interest statement

- Paid employee of Imperial Brands PLC. Views expressed in the document are those of the author and do not necessarily reflect the opinions of Imperial Brands PLC
- The study described within this presentation was solely funded by Imperial Brands PLC. The primary study, data analysis and evaluation was designed and conducted by the Centre for Substance Use Research Ltd & Russell Burnett Research and Consultancy Ltd.
- Not all of Imperial Brands' potential harm reduction products are sold in every market in which we operate, including the US.
- Those products sold in the US are subject to FDA regulation and no reduced-risk or cessation claims will be made as to those products without FDA clearance. The scientific evidence presented here is from a non-US study on a non-US product with non-US consumers.
- None of our NGP are medically-licensed smoking cessation products and are not marketed or sold as such.



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# **Why present UK scientific evidence from a non-US product at FDLI?**

# A call for global scientific collaboration

## TOBACCO HARM REDUCTION IS GLOBAL

**Scientific progress is accelerated when evidence, methodologies and insights are shared.**

## CROSS-REGIONAL LEARNINGS

**Different regulatory pathways can generate complementary evidence.**

## SHARED SCIENTIFIC QUESTIONS

**Understanding consumer behaviour and transition away from smoking.**

## UNIQUE OPPORTUNITY FOR REAL-WORD EVIDENCE

**UK post-market environment enabled Actual Use research.**



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Different regulation, shared goals

**Different regulatory pathways,  
shared public health goals.**

# Different regulation, shared goals



## The US FDA PMTA Framework

- **Product specific** authorisation via PMTA process.
- Focus on **product-specific scientific evidence** to demonstrate APPH.
- Focus on generating **extensive evidence across multiple scientific disciplines**.



## The UK MHRA & EU Tobacco Products Directive

- **Notification-based system** focusing on quality & safety standards.
- **No premarket authorization required** in most countries (including the UK).
- **Post-market surveillance** enables ongoing monitoring & risk mitigation to safeguard consumer & public health.



## WHY IT MATTERS FOR TODAY'S PRESENTATION:

- The study presented was conducted under a **real-world environment regulated to support THR**.
- It offers **complementary insights** into consumer behavior which may be difficult to generate through pre-market research alone.
- Opportunity for **cross-jurisdictional learning** to inform the wider scientific community & global THR strategies.



# Imperial Brands Scientific Assessment Framework



**What's in the aerosol?**



**What's the impact on human cells?**



**What's happening in consumers?**



**What does the consumer actually do?**



**What is the future potential?**



**What is happening in real life?**

**The Behavioural Studies presented here focuses on the consumer behavior in a close to real-world scenario.**



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# From data to insights: how we studied product use in consumers daily lives



## Primary aim capture **consumer journeys**:

Generate robust scientific evidence on how blu 2.0 and blu bar may influence changes in cigarette consumption among UK adult smokers.

## Secondary aim capture **consumer experiences**:

Preferences, satisfaction, risk perception, motivations & interest, and product acceptance.



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# From data to insights: how we studied product use in consumers daily lives



**Sample:** 850 adult UK smokers enrolled. No direction given to use blu or stop smoking.

6-week  
Observational phase

## Innovative & novel methodology:

1. Familiarisation session was designed to simulate the typical vape shop experience that adult smokers may encounter.
2. Pre-funded debit card provided allowing purchase of blu in any flavor directly from retailer of choice.



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# Impact of blu on smoking behavior emerged quickly & was sustained at 24 weeks after free provision of blu ending at week 6

## Consumer journeys



**37–40%**

substantially reduced  
( $\geq 50\%$ ), fully switched to  
blu or stopped  
smoking/using  
blu 2.0\*

- 37% blu 2.0
- 40% blu bar

blu 2.0



of switchers &  
substantial reducers  
were exclusively using  
**non-tobacco flavors**

\* Represents data collected from participants using monitored products. Participants may have used other products not tracked in this study. None of our Next Generation Products are medically-licensed smoking cessation products and are not marketed or sold as such.



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# New insights reveal demographic differences in flavour preference and flavour exploration

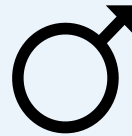
Flavour preferences  
blu 2.0

## Most consumed by flavour category

|         |     |
|---------|-----|
| Fruit   | 53% |
| Menthol | 30% |
| Tobacco | 17% |

Participants who **switched or substantially reduced** cigarette consumption showed a clear preference for **fruit flavours**

## Flavour preferences by gender



**Males:** Stable flavour preferences



**Females:** Greater flavour exploration



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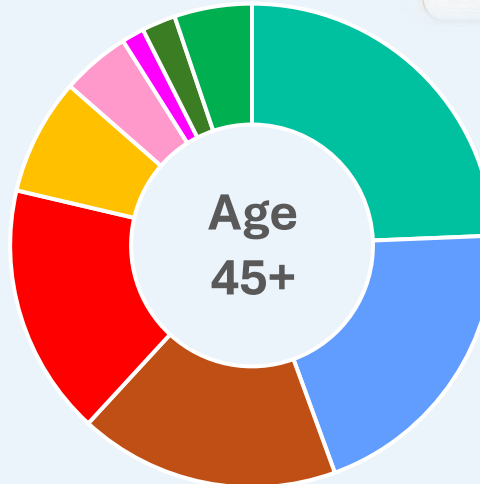
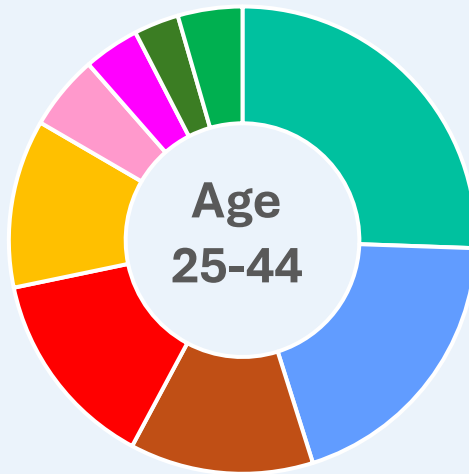
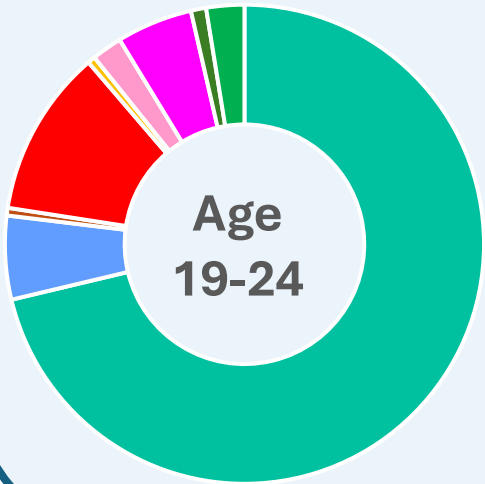
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blu

# Non-tobacco flavour preferences extended across all adult age groups

## Top 3 blu 2.0 flavours consumed

Fresh mint  
Blueberry ice  
Berry mix



Fresh Mint   Blueberry Ice   Golden Tobacco   Berry Mix   Fresh Mango  
Watermelon Ice   Strawberry Mint   Green Apple   Polar Menthol



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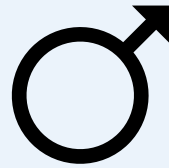
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# Distinct gender differences in flavour exploration were observed among blu bar consumers

## blu bar flavour preference across whole observation period:

|                     |     |
|---------------------|-----|
| Banana Ice          | 13% |
| Blueberry Ice       | 12% |
| Blueberry Sour Razz | 12% |
| Strawberry Ice      | 10% |

## Flavour preferences by gender



### Males

Week 1-2: **Banana Ice**  
Weeks 2-3: **Kiwi Passionfruit**  
Weeks 4-6: **Blueberry Sour Razz**



### Females

Displayed **higher variation** week to week, indicating **more flavour exploration**.



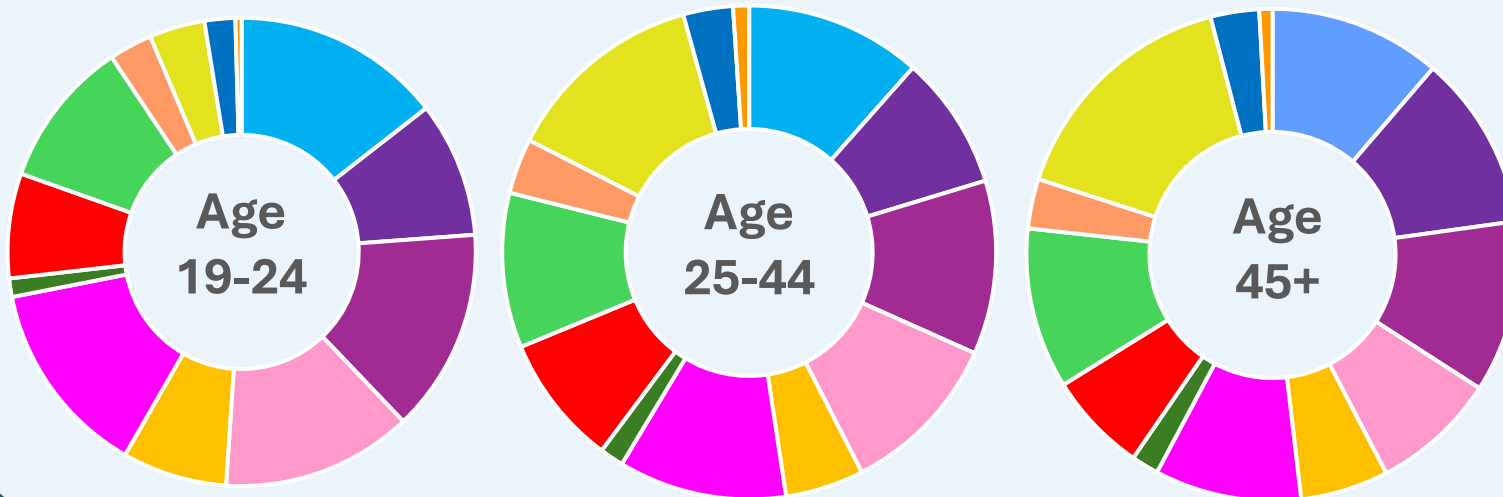
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# Engagement with blu bar flavour variety extended across all age groups

## Flavour use remained diverse across all adult age groups



No individual flavour was **disproportionately concentrated** within any age group

**Similar levels of flavour diversity** observed among adults aged 19-24, 25-44 and 45+

■ Blueberry Ice ■ Grape Ice ■ Blueberry Sour Razz ■ Watermelon Ice ■ Mango Ice  
■ Strawberry Ice ■ Apple Ice ■ Berry Mix ■ Kiwi Passionfruit ■ Peach Ice  
■ Banana Ice ■ Mint ■ Tropical Mix

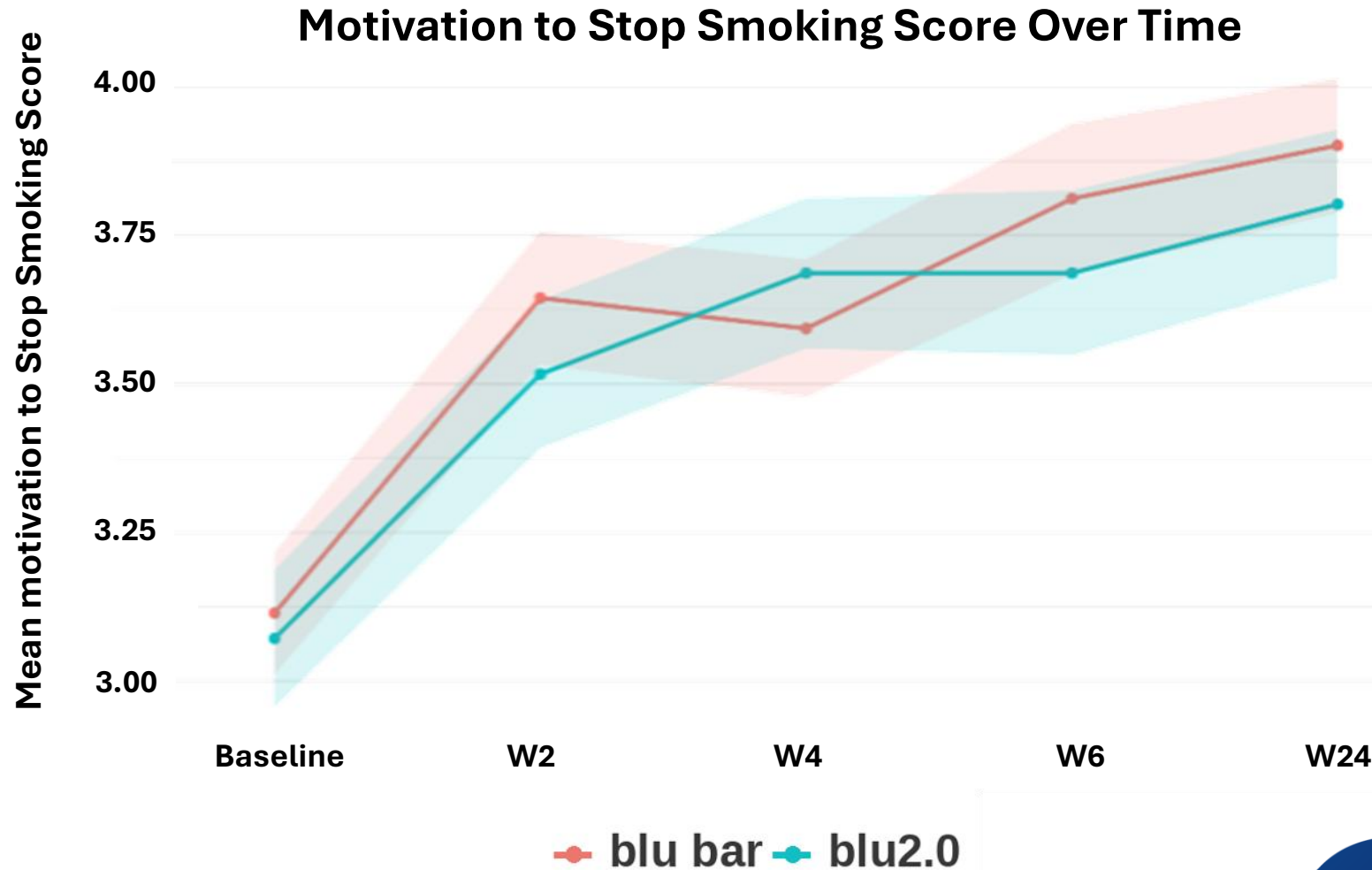


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# Motivation to stop smoking (MTSS) increased over time and was associated with successful behavioural outcomes



**Progressive increase** in the average MTSS over the 24-week period, with the **most significant rise** occurring **between baseline and week 2**.

Participants who switched reported **significantly higher motivation** than non-switchers

**blu 2.0:** Participants with higher MTSS were **significantly** more likely to **show a positive behavioral change**



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# Behaviour change appeared to be influenced by a combination of both motivation and lived product experience



## blu 2.0

### 6 weeks

Motivation to Stop Smoking

Urge to Smoke

Relief from Cravings



## blu bar

### 6 weeks

Puffs per day

Motivation to Stop Smoking

Urge to Smoke

Risk Perceptions

Relief from Cravings

Satisfaction

All of these variables were able to significantly predict change in cigarettes per day (CPD) at week 6 relative to baseline.



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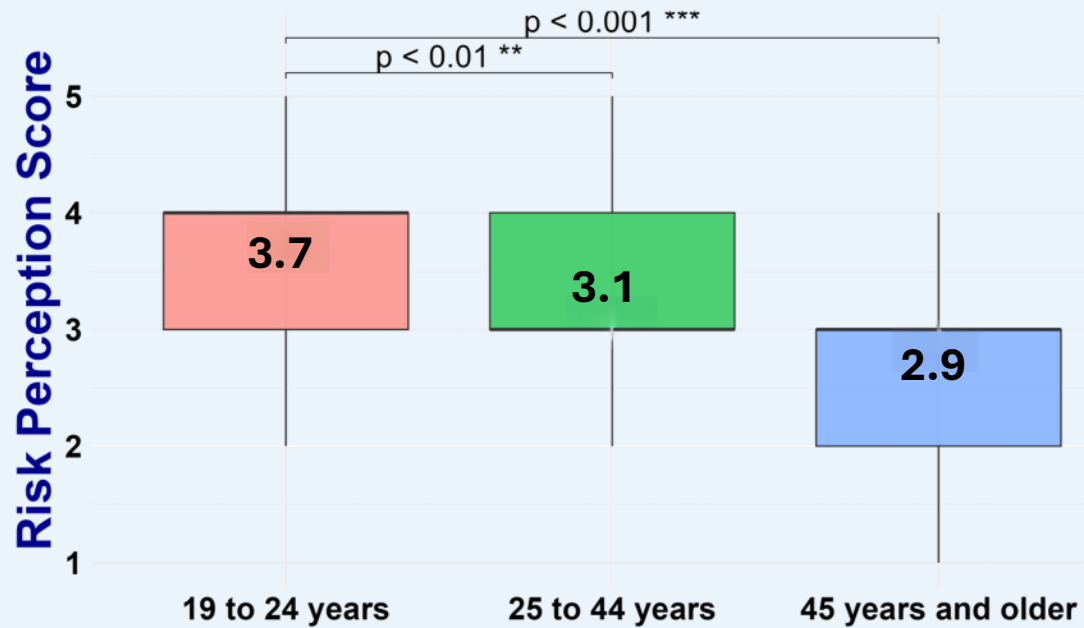
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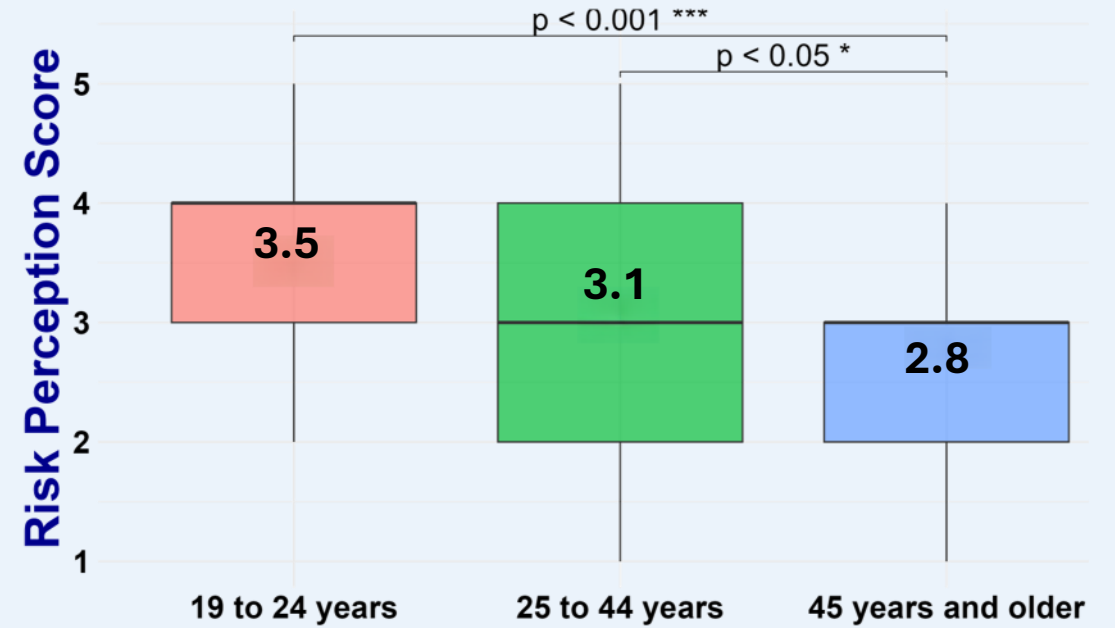
# Perceived harm was consistently higher among younger adults



**blu 2.0**



**blu bar**



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# Relative risk perceptions were associated with successful behavioural transitions



**Key insight:** Accurate relative risk perceptions were linked to greater likelihood of positive behavioral change among adults who smoke.

In general participants rated vaping **as less harmful** than smoking

**blu 2.0:** Older adults who smoke were **more likely** to report accurate **relative risk** perceptions of vaping vs younger adult participants

More **accurate perceptions** of relative risk were **associated with a higher** probability of switching or reducing cigarettes per day



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## In Conclusion

- **Flavour variety** emerged as an important feature of the consumer journey with non-tobacco flavours being used across the adult age spectrum.
- Relative **risk perceptions impact behavioural outcomes**, highlighting the importance of clear, accurate and accessible risk communication.
- Successful behavioural transition appears to be influenced by a combination of **motivation, lived product experience and consumer perceptions**.

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# Secondary Analysis of blu bar and blu 2.0 Actual Use Studies