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An Actual Use Study of a Rechargeable Pod-Based ENDS Product and Changes in Cigarette Smoking Behavior Among Adult Smokers in the United Kingdom

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FDLI Tobacco and Nicotine Products
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Disclaimer & Conflict of Interest statement

Paid employees 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 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.

None of our NGP are medically-licensed smoking cessation products and are not marketed or sold as such.

The scientific evidence presented here is from a non-US study on a non-US product with non-US consumers and unrelated to any potential ITGB regulatory initiatives in the US.



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Introduction

**Why are we
presenting scientific evidence from
a study on a non-US product,
conducted in a non-US country,
with non-US consumers?**

We are committed to Tobacco Harm Reduction



IMPERIAL BRANDS IS COMMITTED TO SUBSTANTIATE OUR PRODUCTS

With this scientific study we substantiate the potential contribution of our blu ENDS to public health.



IMPERIAL BRANDS IS COMMITTED TO CONTRIBUTE TO THE SCIENTIFIC DEBATE

This scientific study addresses the important (general) question on the role of flavors in Tobacco Harm Reduction (THR).



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A call for global scientific collaboration



WE ARE HERE TO CONTRIBUTE

We want to enrich the US scientific dialogue on Tobacco Harm Reduction from a non-US perspective.



CROSS-REGIONAL LEARNING IS KEY

Understanding how ENDS perform within different regulatory frameworks can help (re)shape thinking.



BEHAVIORAL SCIENCE IS UNIVERSAL

Scientific approaches to assess Human behaviour around nicotine use apply across global borders.



HARM REDUCTION IS GLOBAL

THR is too important to public health to be siloed – scientific data sharing and collaboration is vital.



Different rules, shared goals

What are the different regulatory environments around nicotine products in the US and Europe, and why do they matter here?

Different rules, shared goals



The US FDA / PMTA Framework

- Product-by-product approval via PMTA process.
- Focus on product-specific scientific evidence to prove APPh.
- Focus on toxicology, clinical & behavioral impact, population health modeling.



The UK MHRA & EU Tobacco Products Directive

- Notification-based system with 6-month pre-market notification focusing on quality standards.
- No premarket authorization required in most countries (including the UK).
- Post-market surveillance is vital to the UK MHRA framework for nicotine vaping products, enabling ongoing monitoring and risk mitigation to safeguard consumer and 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 and patterns of use under different regulations.
- The outcomes may **encourage cross-jurisdictional learning** to inform global THR Strategies.



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The scientific context

**Where does this Behavioral Study
sit in Imperial's approach to assessing
the potential for Tobacco Harm Reduction?**

Our Scientific Assessment Framework



Imperial's multi-stage, multi-discipline Scientific Assessment Framework evaluates Product Safety and substantiates the Harm Reduction potential of our NGP relative to cigarettes.



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Let's start with our consumers



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 Study presented here focuses on the consumer behavior in a close to real-world scenario.



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blu 2.0 Actual Use Study

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 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

Study Design

Recruitment

Site Visit 1

Baseline

Site Visit 2

Enrolled

Sample: 429 adult UK smokers enrolled. No direction given to use blu 2.0 or stop smoking.

6-week
Observational phase



Week 24 follow up post enrolment

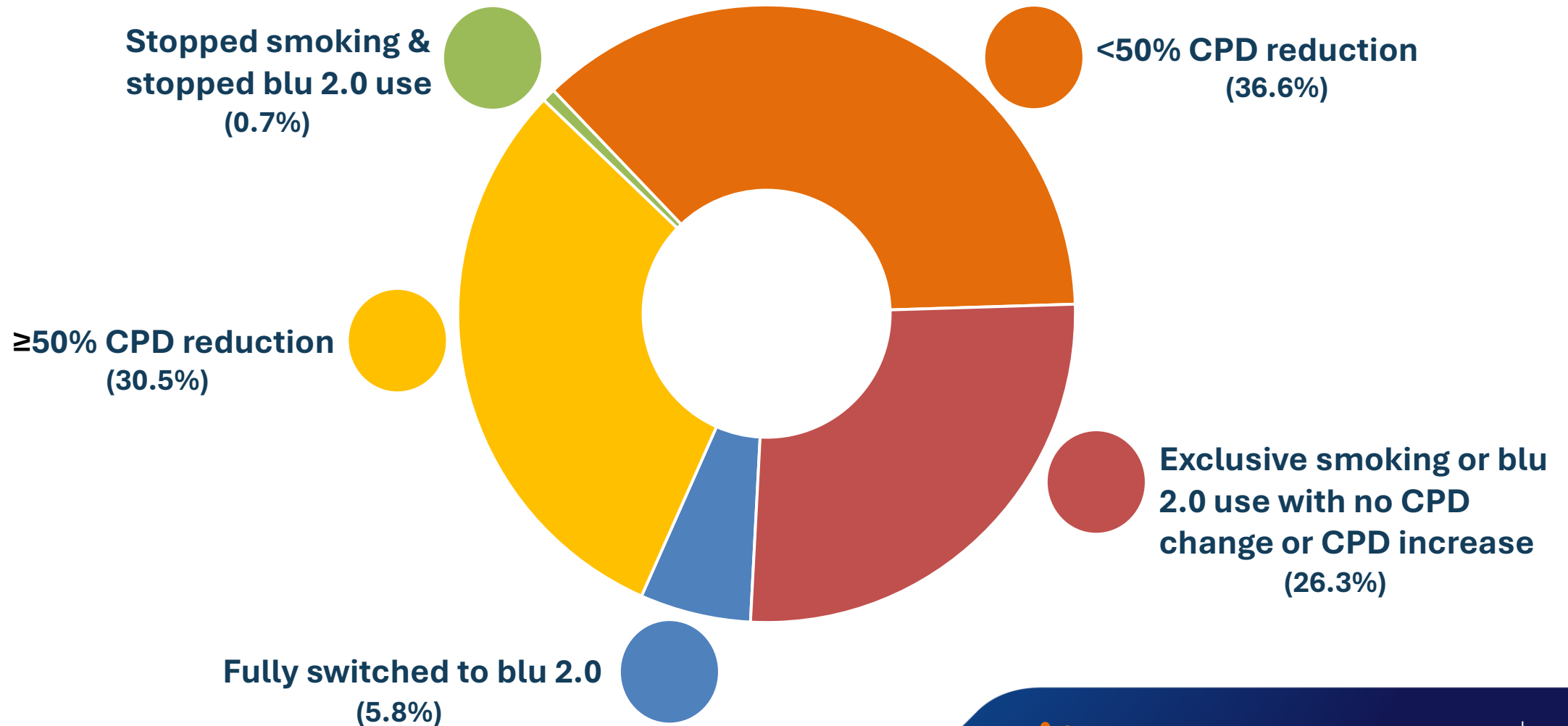
Innovative & novel methodology:

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 2.0 in any flavor directly from retailer of choice.



Five categories of behavior observed during the study

Consumer journeys
Week 6



CPD - Cigarettes per day



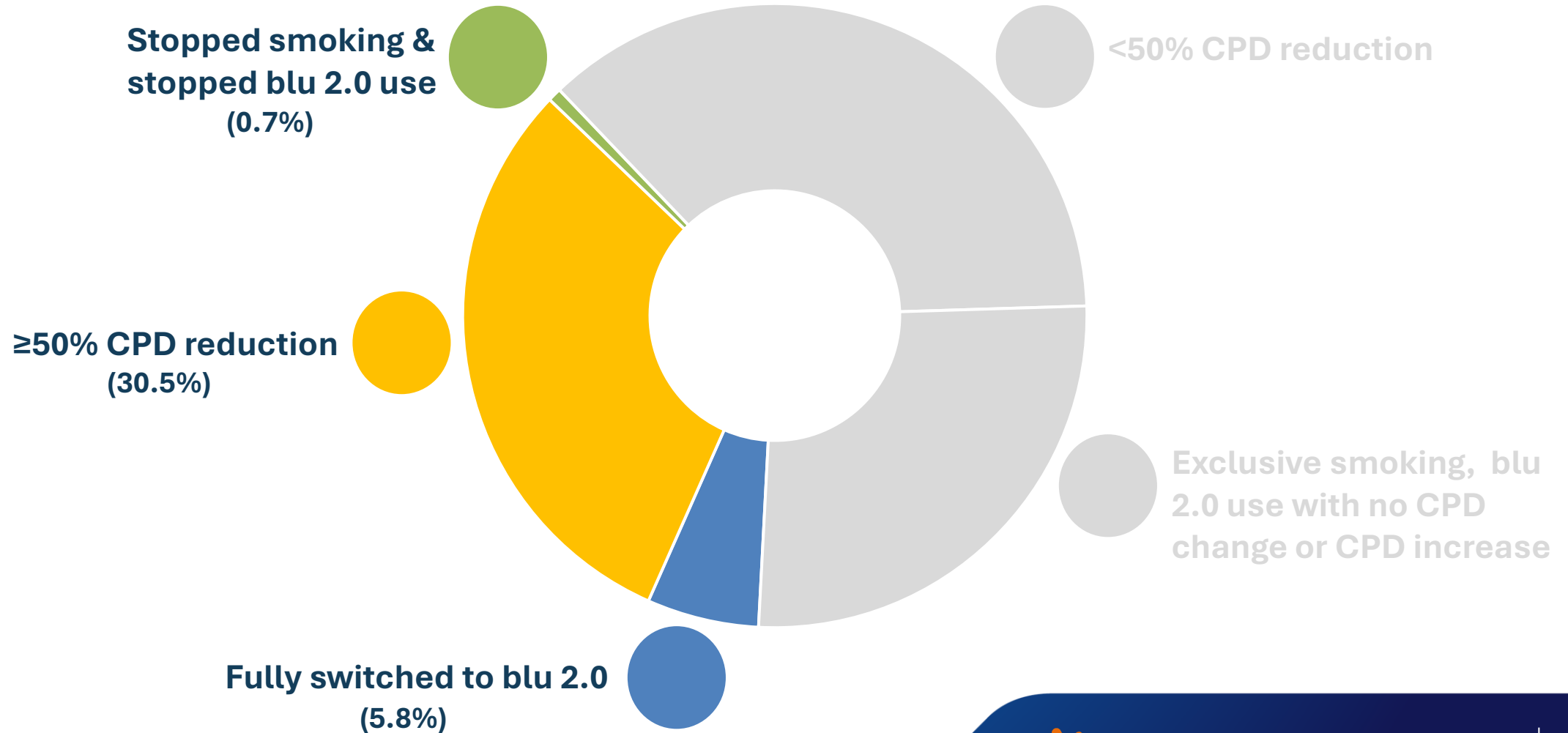
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The potential impact of blu 2.0 on smoking behavior emerged quickly

Consumer journeys Week 6



CPD - Cigarettes per day



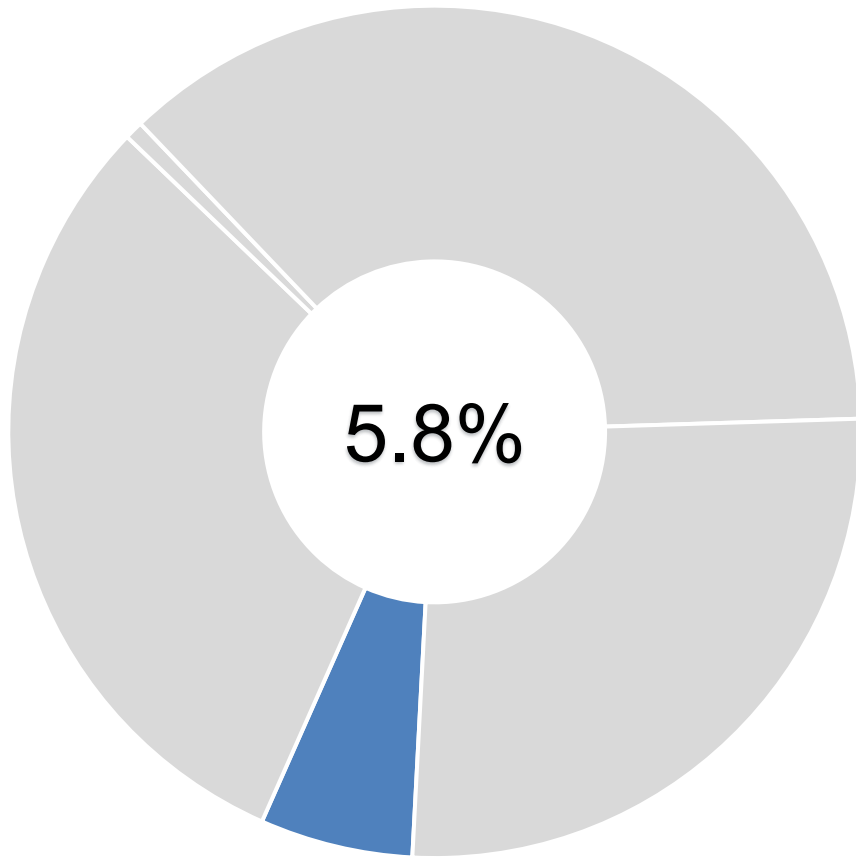
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After 6 weeks 5.8% of smokers fully switched to blu 2.0

Consumer journeys
Week 6



Fully switched to blu 2.0 & quit smoking cigarettes



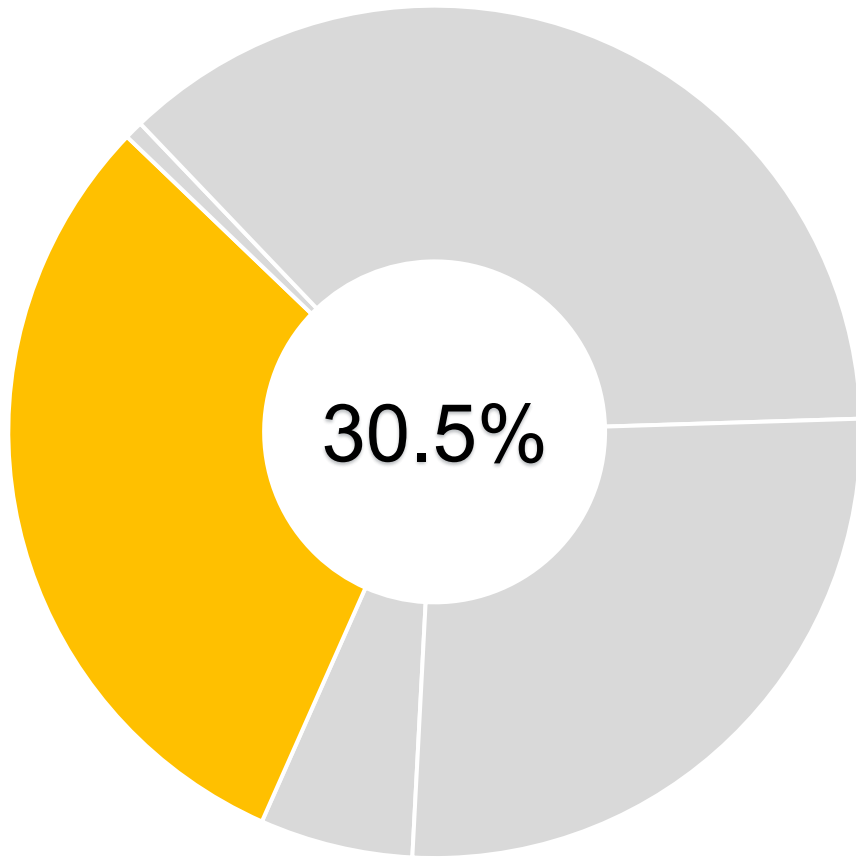
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Approximately 1 in 3 smokers substantially reduced smoking
by 50% or more

Consumer journeys
Week 6



Substantially reduced CPD $\geq 50-99\%$



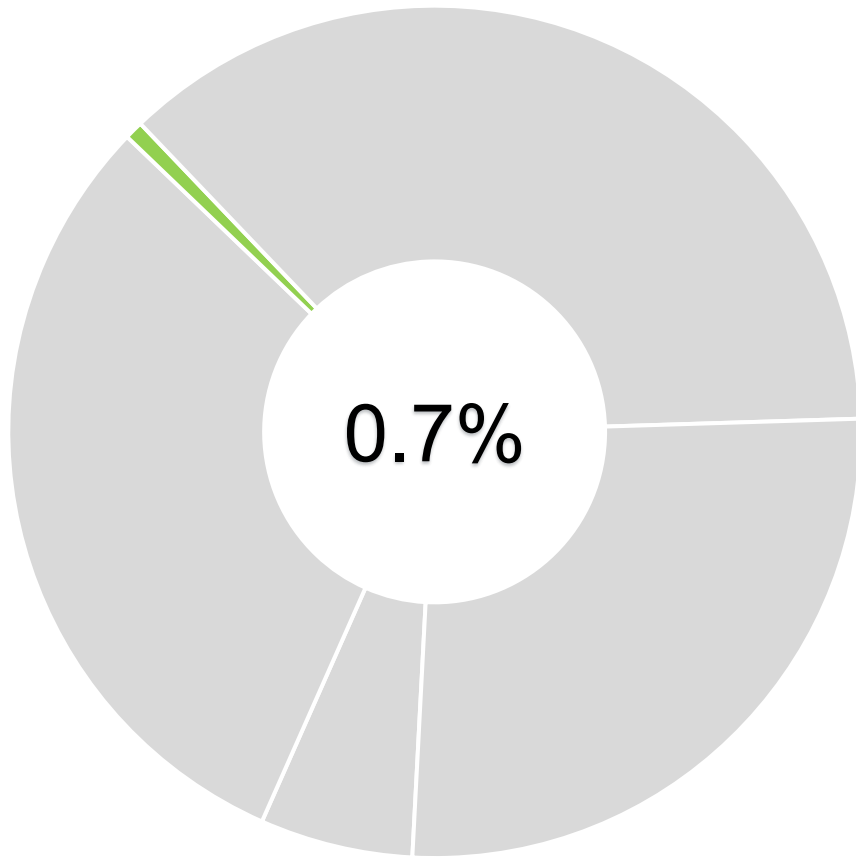
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A small proportion of smokers stopped smoking and using blu 2.0 completely

Consumer journeys
Week 6



Stopped smoking & stopped using blu 2.0

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



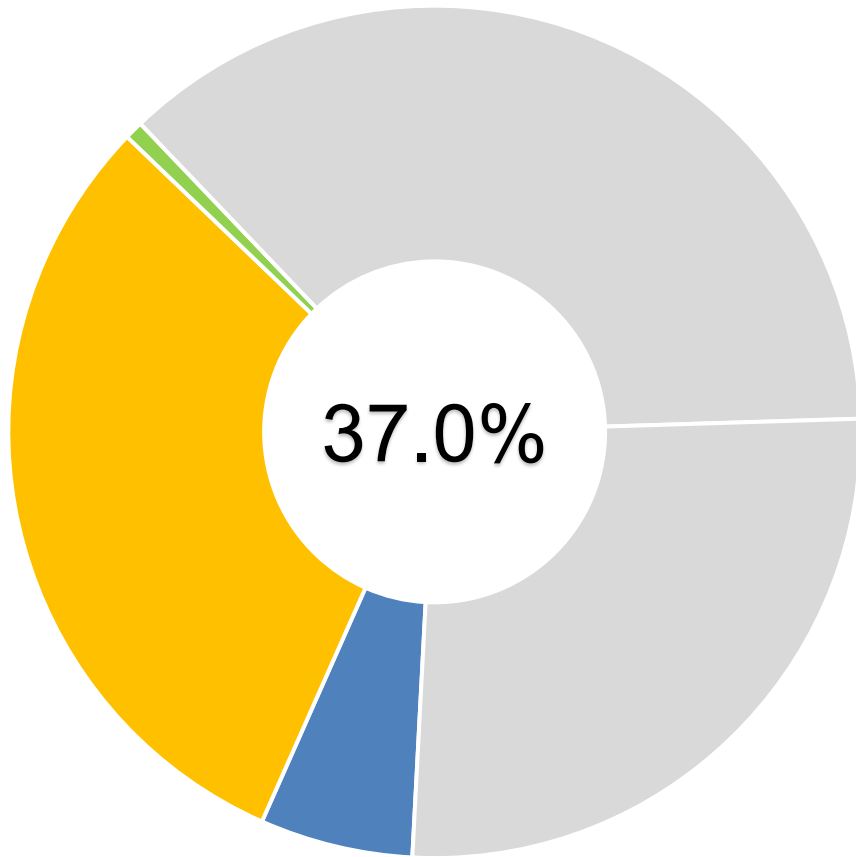
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By week 6, 37% of smokers showed meaningful behavioral changes

Consumer journeys
Week 6



Fully switched to blu 2.0, substantially reduced CPD ($\geq 50-99\%$) or, stopped smoking/using blu*

* Represents data collected from participants using monitored products. Participants may have used other products not tracked in this study.



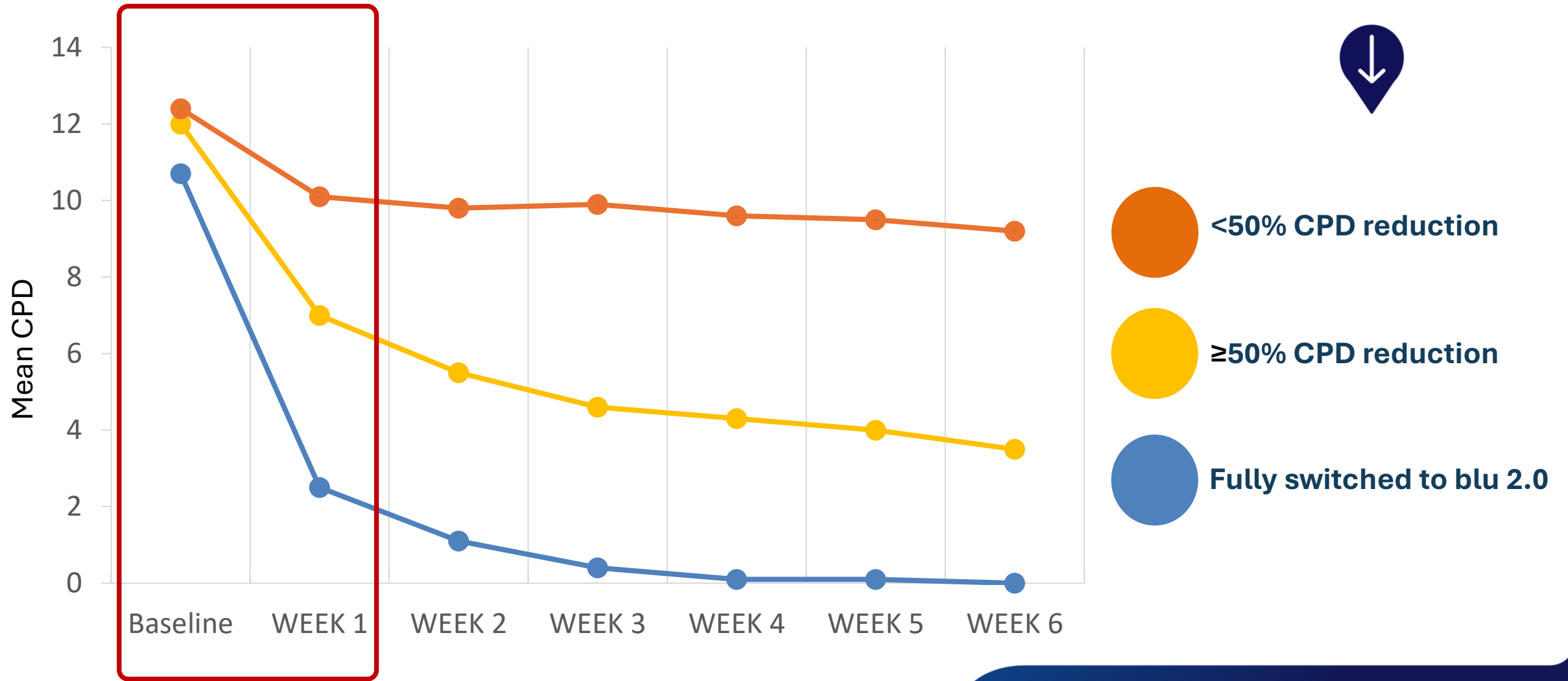
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Impact of blu on smoking behavior emerged quickly: Majority of smoking reduction occurred during week 1

Consumer journeys Week 6



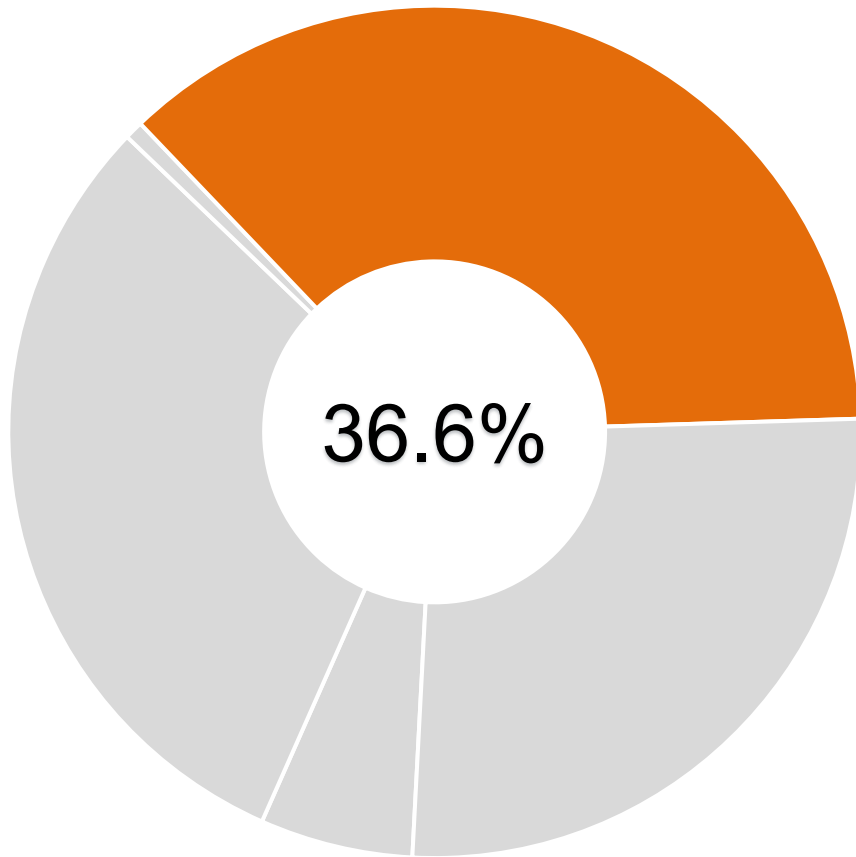
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Broader impact: one-third of smokers reduced CPD <50%

Consumer journeys
Week 6



<50% reduction in CPD



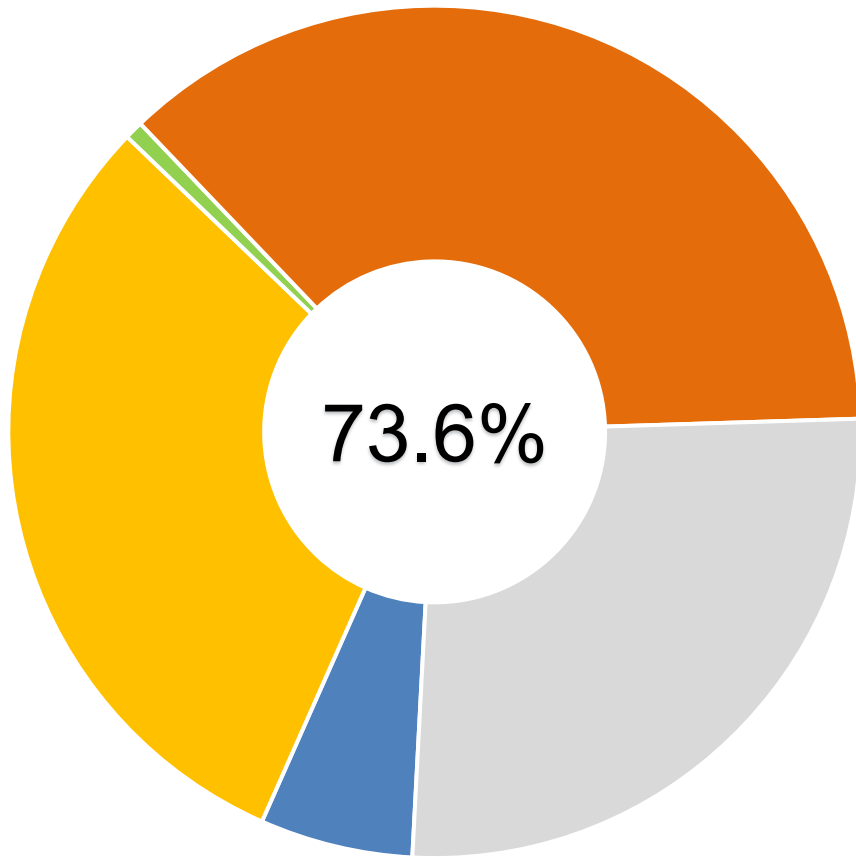
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Broader impact: introduction, familiarisation & use of blu 2.0 associated with smoking reduction in the majority of participants

Consumer journeys Week 6



Fully switched to blu 2.0,
reduced CPD, or stopped
smoking/using blu*

Overall: across 6 week

Per participant;

- On average 33.6% reduction in total cigarette consumption
- Approx. 8.4 fewer packs of cigarettes smoked vs counterfactual week

In the context of this study the
totality of changes over 6 weeks:
Estimated >70,000 fewer
cigarettes smoked

* Represents data collected from participants using monitored products. Participants may have used other products not tracked in this study.



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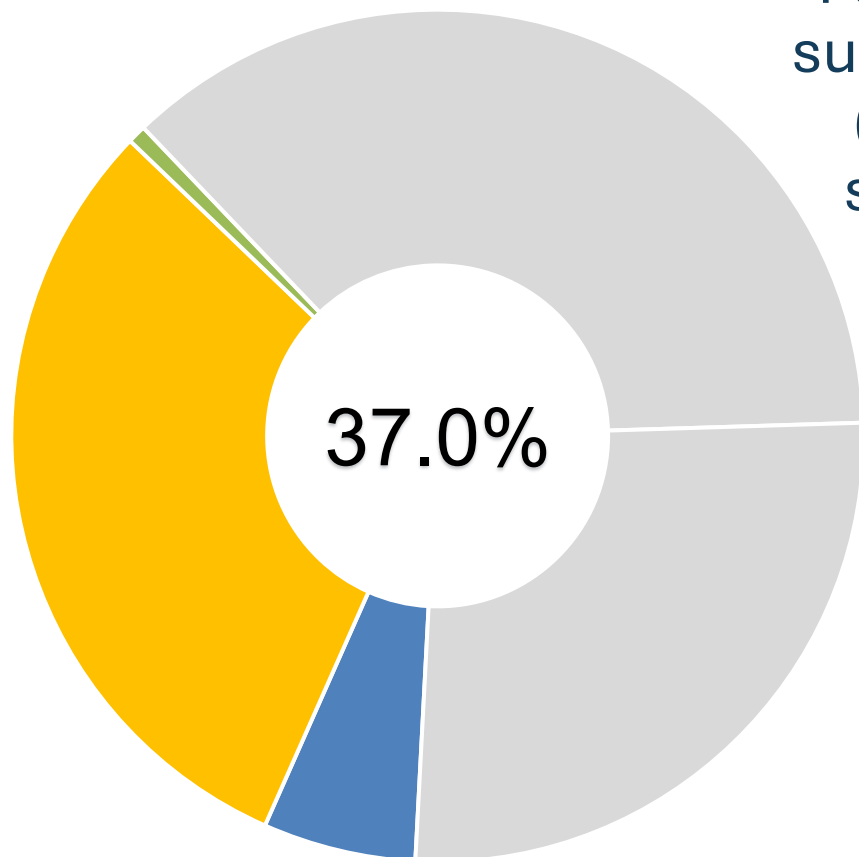
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Findings were broadly maintained at week 24

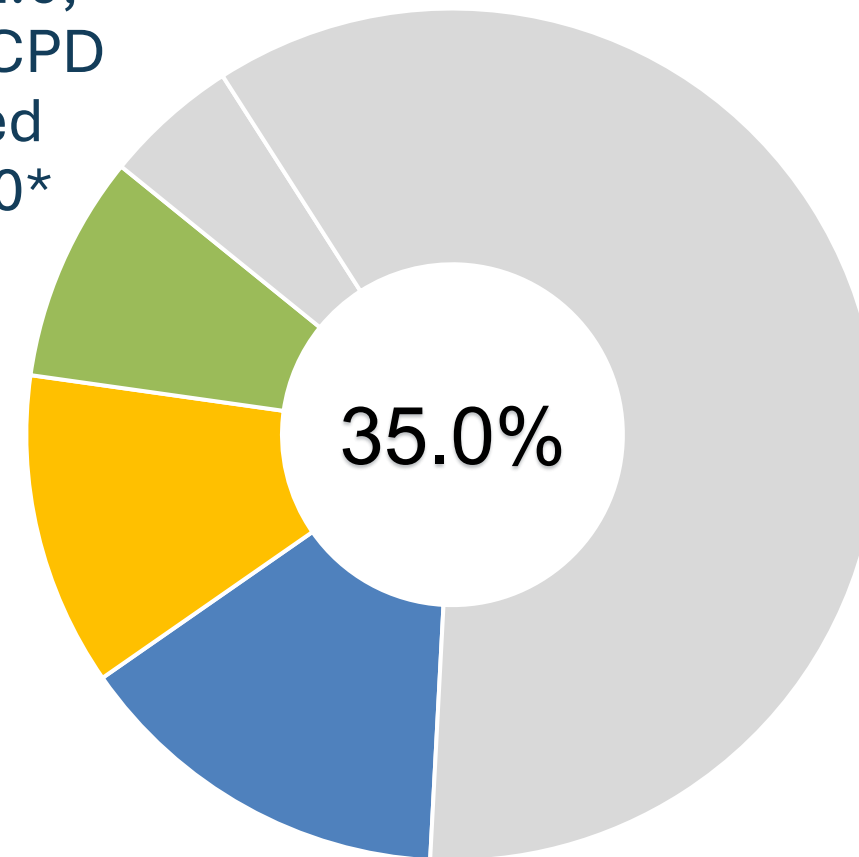
Consumer journeys Week 24

Week 6



Fully switched to blu 2.0,
substantially reduced CPD
($\geq 50-99\%$), or stopped
smoking/using blu 2.0*

Week 24



* Represents data collected from participants using monitored products. Participants may have used other products not tracked in this study.



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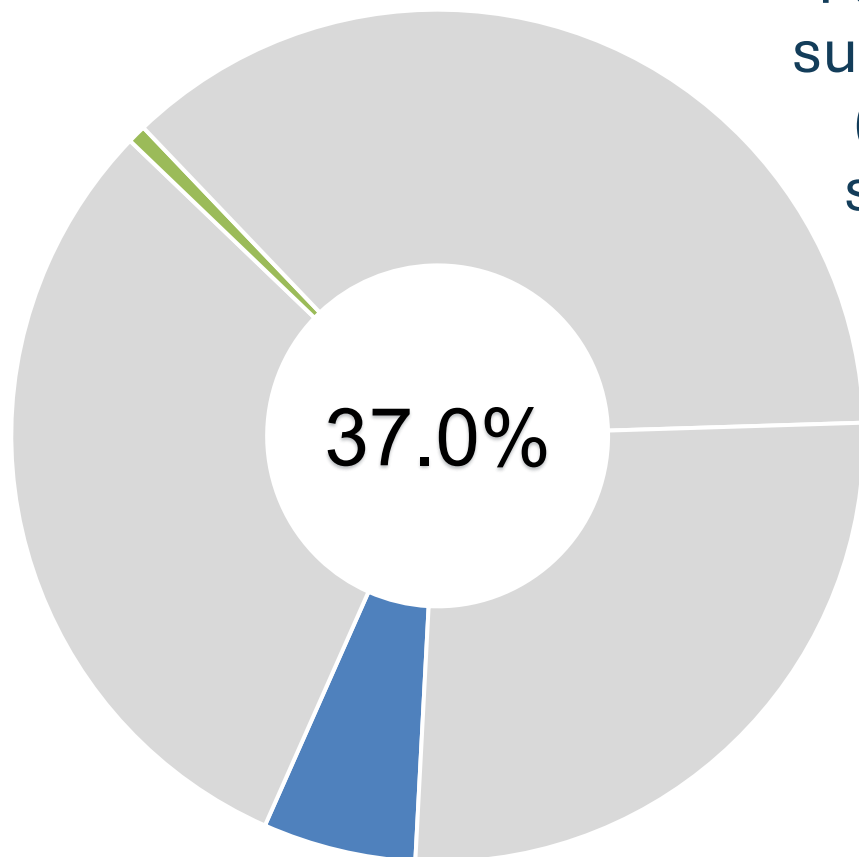
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Findings were broadly maintained at week 24

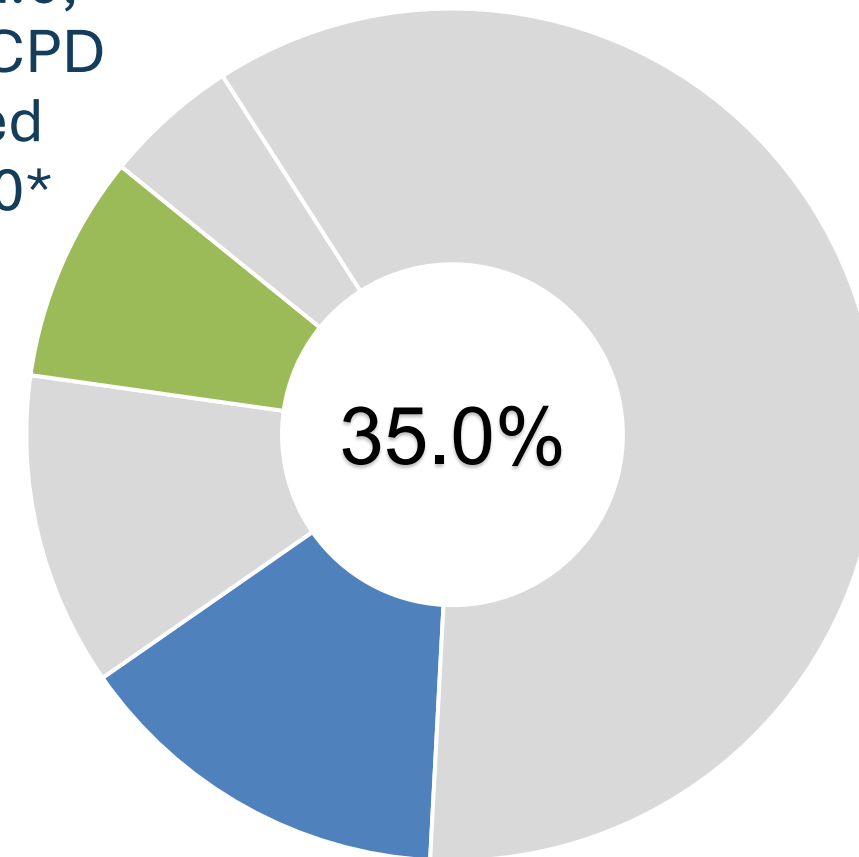
Consumer journeys Week 24

Week 6



Fully switched to blu 2.0,
substantially reduced CPD
(≥ 50 -99%), or stopped
smoking/using blu 2.0*

Week 24



* Represents data collected from participants using monitored products. Participants may have used other products not tracked in this study.



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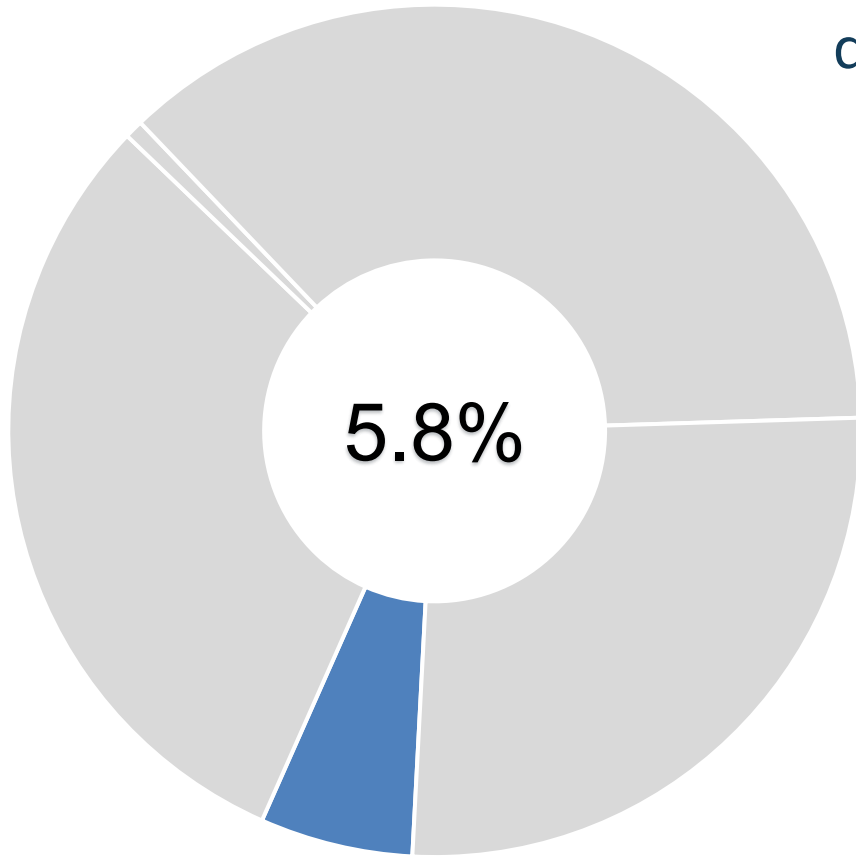
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Switching momentum builds with those using blu 2.0 at week 24 more than doubling

Consumer journeys
Week 24

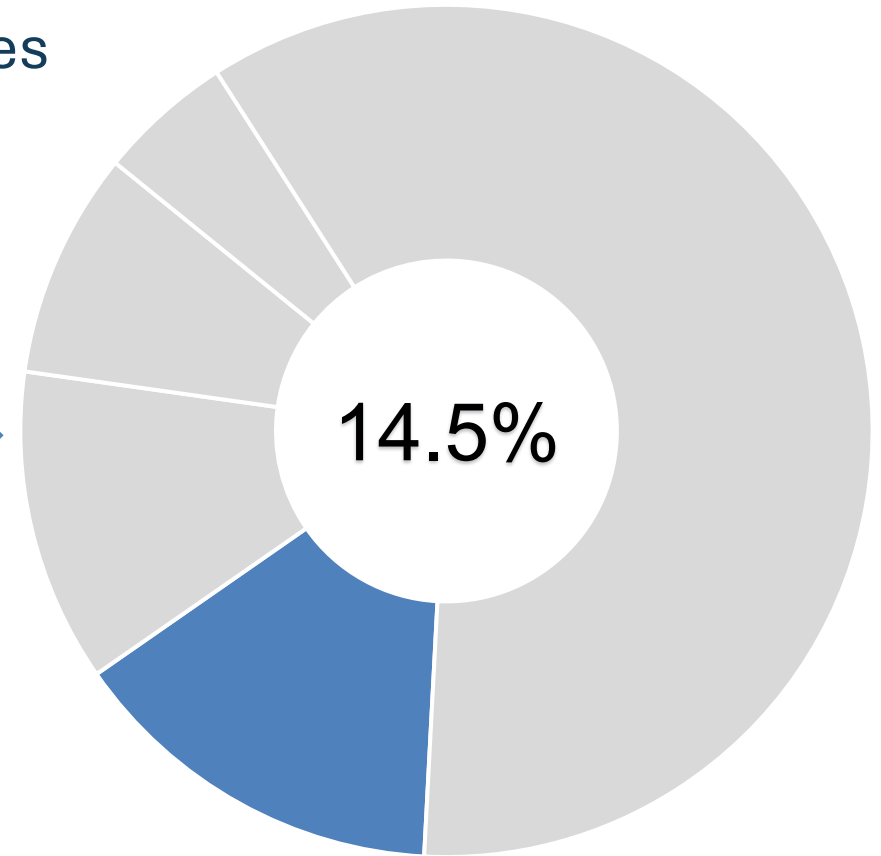
Week 6



Fully switched to blu 2.0 &
quit smoking cigarettes

150% increase

Week 24



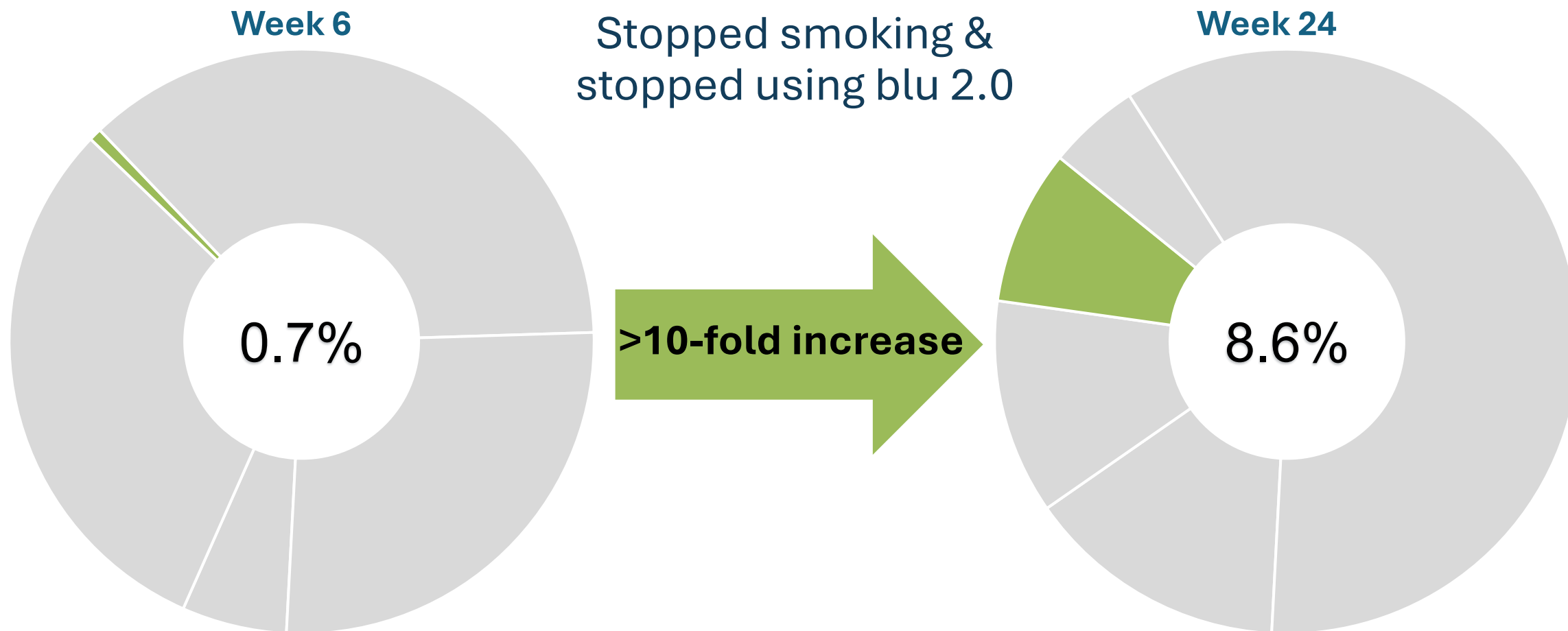
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Almost an additional 1 in 10 reporting not smoking or using blu 2.0

Consumer journeys
Week 24



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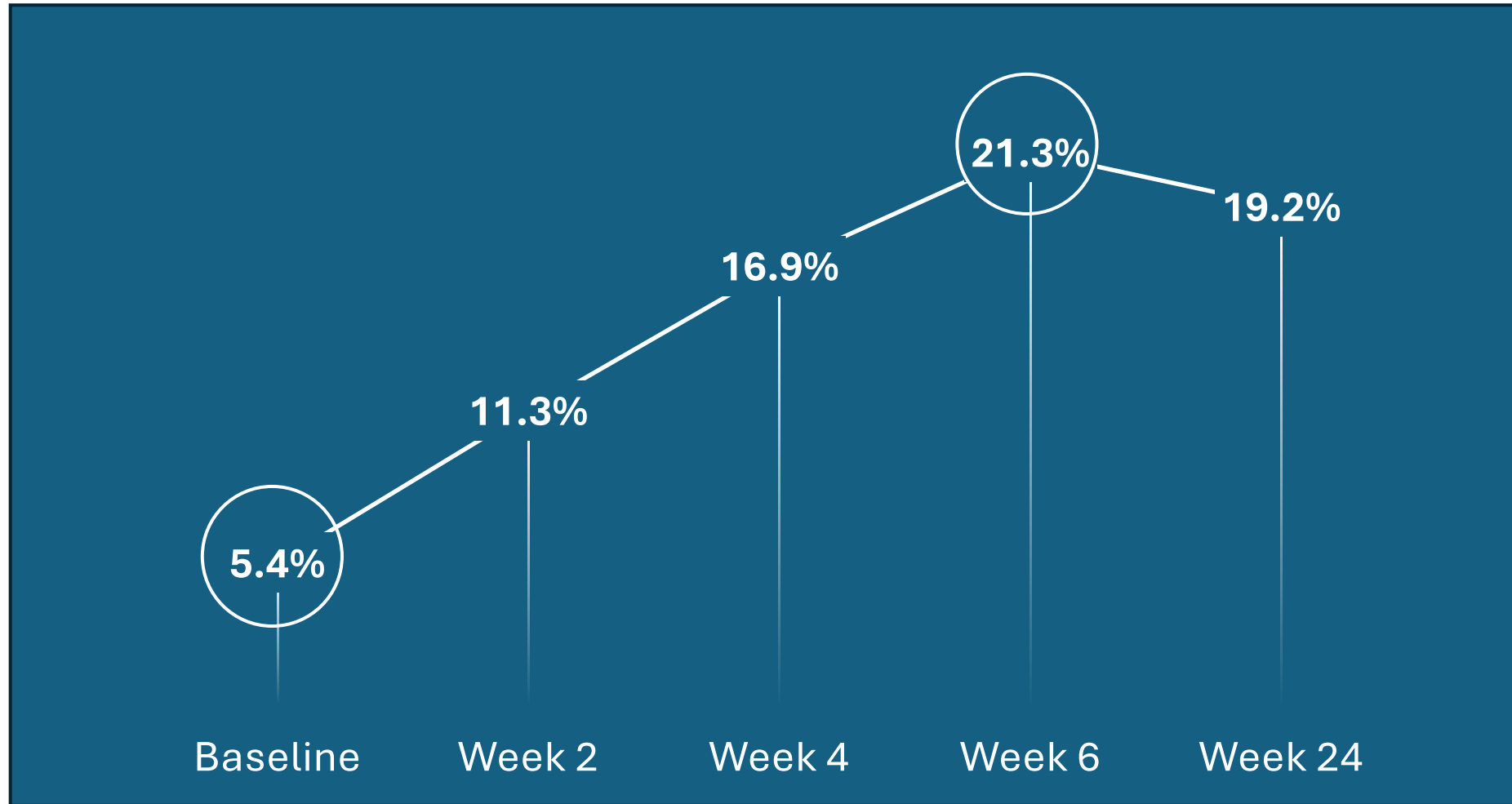
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Beyond product use changes: Rapid rise in motivation to quit from 5% to 21% in 6 weeks with lasting impact at follow up

Consumer journeys



None of our NGP are medically-licensed smoking cessation products and are not marketed or sold as such



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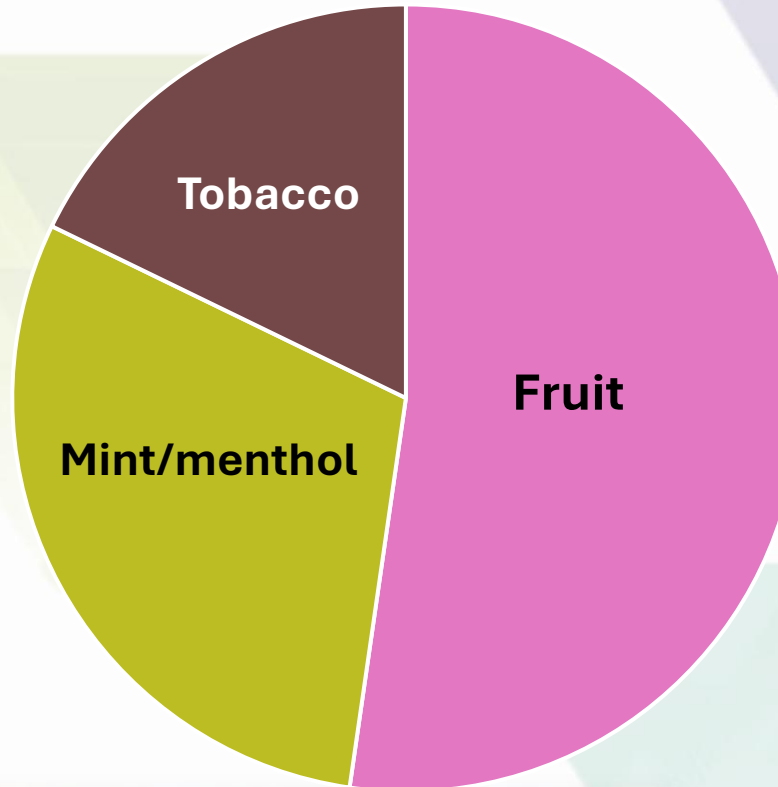
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A broad range of flavors was a significant driver in altering smoking behavior & remained the prominent reason for continued use

Consumer experience

Flavor group consumed
Week 6



Non-tobacco
flavored pods were
13x MORE
POPULAR
Than Golden Tobacco Pods
During Week 6

Flavors & variety

Key reason given for
initial interest &
positive purchase
intentions



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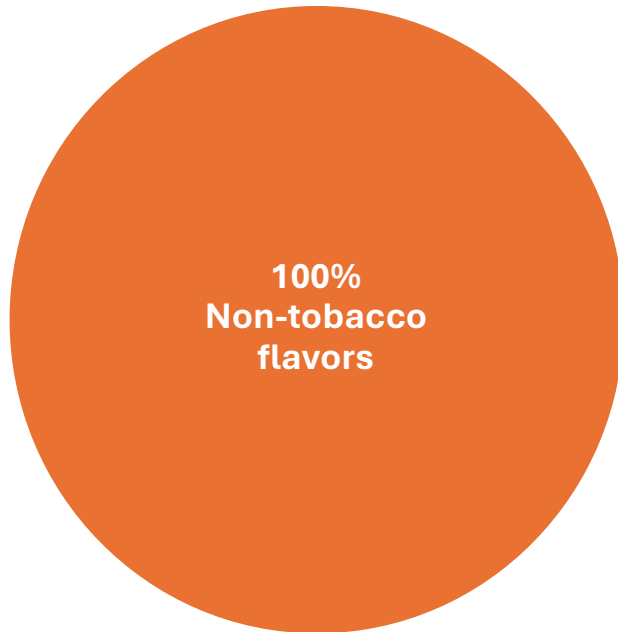
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Non-tobacco flavors contributed to substantial changes in smoking behavior & were exclusively used by all who quit smoking

Consumer experience

Flavors used at Week 6

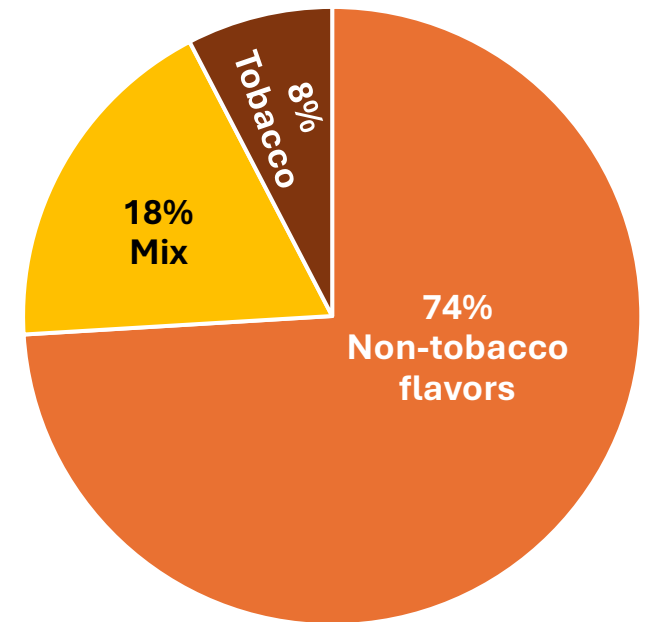
Fully switched to blu 2.0



ALL who **fully switched to blu 2.0** & quit smoking cigarettes **exclusively** used **non-tobacco flavors**

78% of participants who **fully switched to blu or substantially reduced** smoking were **exclusively** using **non-tobacco flavors**.

Substantially reduced smoking



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blu 2.0 scores highly for satisfaction, ease of use and reducing the urge to smoke

Consumer experience

What about consumer experience?

Strength areas

- Satisfaction
- Ease of use
- Comfort using in public
- Cigarette cravings relief & withdrawal symptoms
- Accurate relative risk perception
- Low aversive effects
- Low concern of dependence

Potential refinement opportunities

- Psychological reward
- Disposal
- For a small proportion - blu didn't satisfy "like a regular cigarette"



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blu 2.0 has significant potential to support adult smokers reduce or replace smoking



Results demonstrate consumers find blu 2.0 **satisfying** and has **significant potential to help adult smokers** to completely stop or substantially reduce smoking

The **broad range of flavors** used appear to **contribute to substantial changes in smoking behavior**. This may indicate different flavors may appeal to different smokers and their differing needs

Findings demonstrate the **significant potential** for blu 2.0 to make a **meaningful contribution** to tobacco harm reduction

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Actual Use Study
blu 2.0

Thank you for your
attention