



Actual Use Study of a Heated Tobacco Product (glo™)

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OUTLINE

- 1 Objectives
- 2 Method & Study Design
- 3 Results
- 4 Conclusion



Objectives

Describe the acceptance of the HTP IP (i.e., glo™) and the pattern of CC consumption in the context of the glo™ availability among current daily cigarette smokers.

PRIMARY ENDPOINT 1

Determine number and proportion of subjects who meet the definition of “established users” of the glo™ (defined as using ≥ 100 neo sticks) over the 6 weeks of the AUP.

PRIMARY ENDPOINT 2

Determine number and proportion of subjects among “established users” who reduce their cigarettes per day (CPD) consumption by at least 50% at the end of the AUP.

PRIMARY ENDPOINT 3

Descriptive weekly average CPD consumption per subject among all subjects.

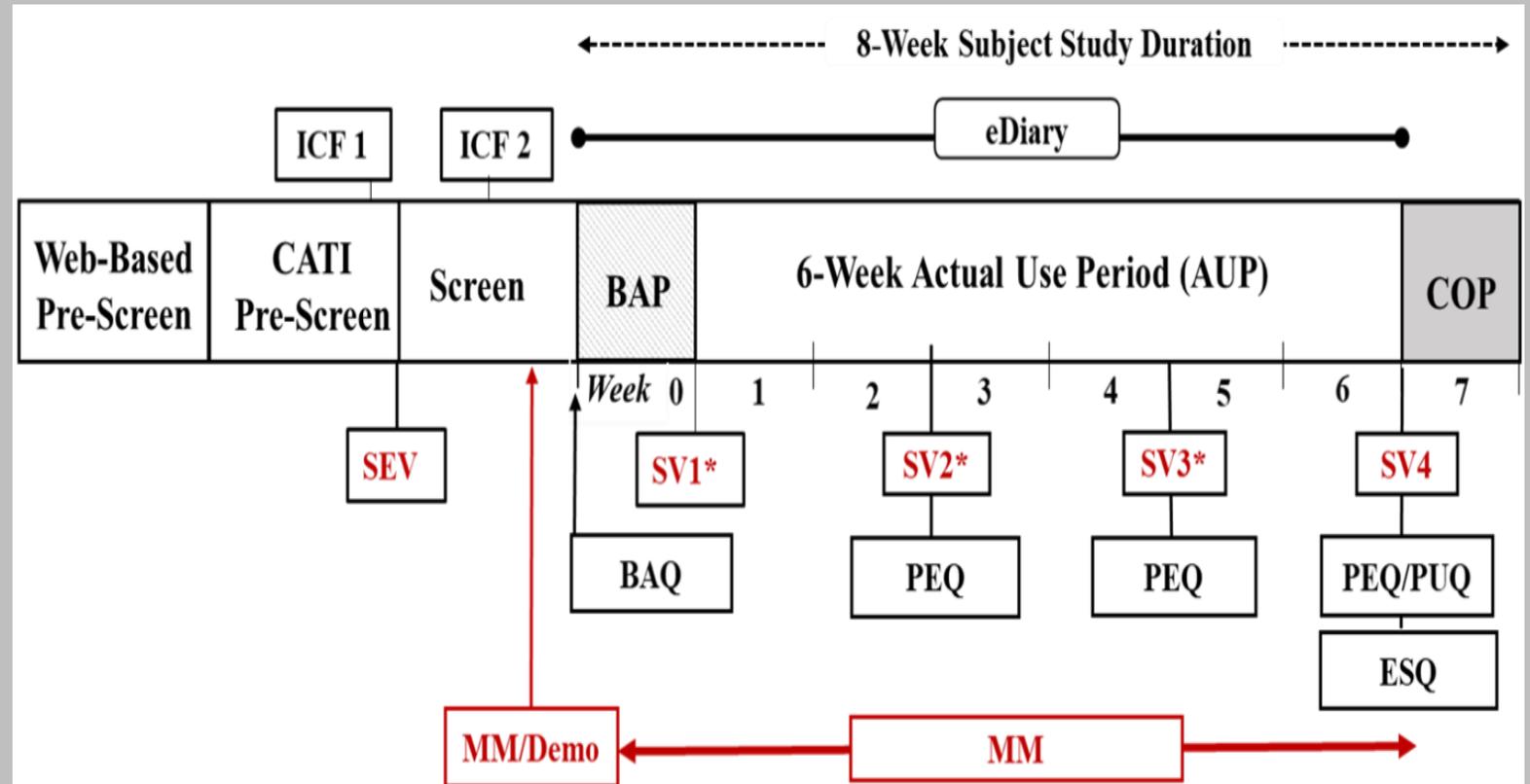
Methods & Study Design

Key Inclusion Criteria:

Adult smokers (defined as ≥ 5 CC/day, smoked 100 CC in lifetime and at least 20/30 days smoked in the past month). Must indicate “an intention to use” glo™ and able and willing to comply with all study requirements.

Study IP:

Heated Tobacco Product (glo glo™) is an alternative to combustible TNPs that can be used with non-combusted neosticks to heat rather than burn tobacco.



* Study IP Distribution

BAP = Baseline Assessment Period
 BAQ = Baseline Assessment Questionnaire
 CATI = Computer-Assisted Telephone Interview
 ESQ = End-of-Study
 COP = Close Out Period
 ICF = Informed Consent Form

ICF = Informed Consent Form
 MM = Marketing Materials
 PEQ = Product Experience Questionnaires
 PUQ = Product Use Questionnaire
 SEV = Screening and Enrollment Visit
 SV = Site visit

DEMOGRAPHICS

Enrolled = 1180*

Full Analysis Set = 1120**

- Fulfilment of all eligibility criteria
- ≥1 documented use of CC in the BAP
- ≥1 documented use of glo in the AUP

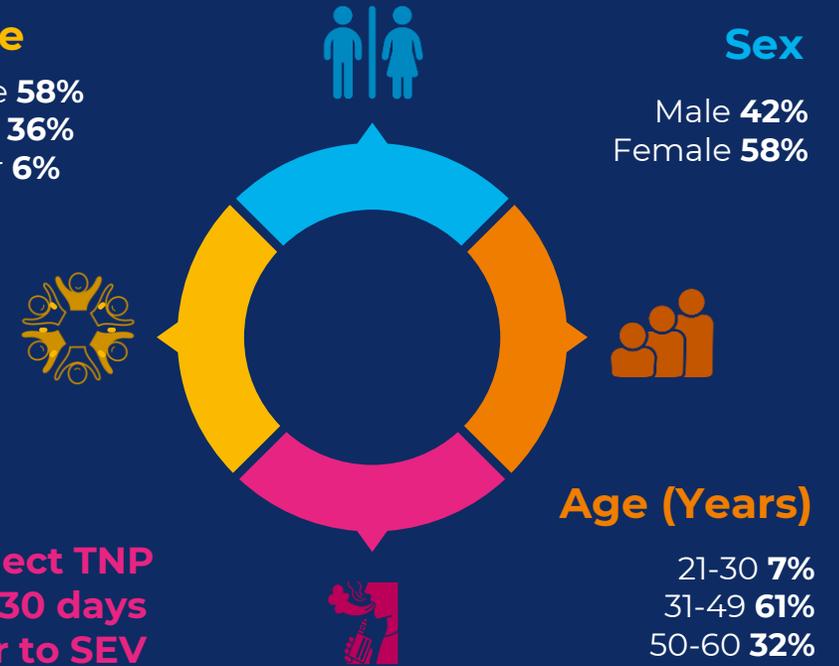
Completed = 1073***

Race

White **58%**
Black **36%**
Other **6%**

Sex

Male **42%**
Female **58%**



* 1229 subjects attended the SEV, 49 screen fails occurred

** 60 enrolled subjects not included in the FAS as did not meet the criteria

*** 47 subjects were terminated early mainly due to lost to follow-up, followed by non-compliance with eDiary

COMPLIANCE RATES

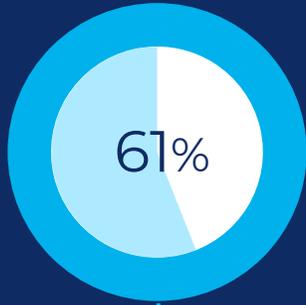
Numbers of Subjects fulfilling compliance criteria	n (%)
Number of subjects with eDiary entries available for at least 6 days of the one-week baseline period	1094 (97.7%)
Number of subjects with eDiary entries available for at least 6 days per week during the six-week Actual Use Period	877 (78.3%)
Number of subjects who did not miss any Site Visit	1014 (90.5%)

SAFETY REPORTING

Less than
1% of
subjects
reported
an AE



Primary Endpoints



PROPORTION OF ESTABLISHED USERS OF GLO™

660 subjects met the definition of established users* of glo™ by Week 6



50% CPD CONSUMPTION REDUCTION

236 established users of glo™ reduced their CPD consumption by at least 50% or more by Week 6



AVERAGE CPD REDUCTION

Average CPD of all completed subjects (n=1073) decreased from 12.4 at baseline to 8.99 at Week 6

* Established users defined as using ≥ 100 neo sticks over AUP.

Note: Results are based on preliminary data

GLO™ USE

4.5 Neo Sticks Per Day at Week 6 (All Completed Subjects)
6.8 Neo Sticks Per Day at Week 6 (Established Users)

INTENT TO USE GLO™ AGAIN

Subjects were asked about their intent to use glo™ again at the end of the study on a scale of 1-10 (1 being definitely would not use it and 10 being definitely would use).

- ❑ 130 subjects (12.1%) reported they would 'definitely use it again'.
- ❑ 573 subjects (53.4%) reported they would use it again (6-10).

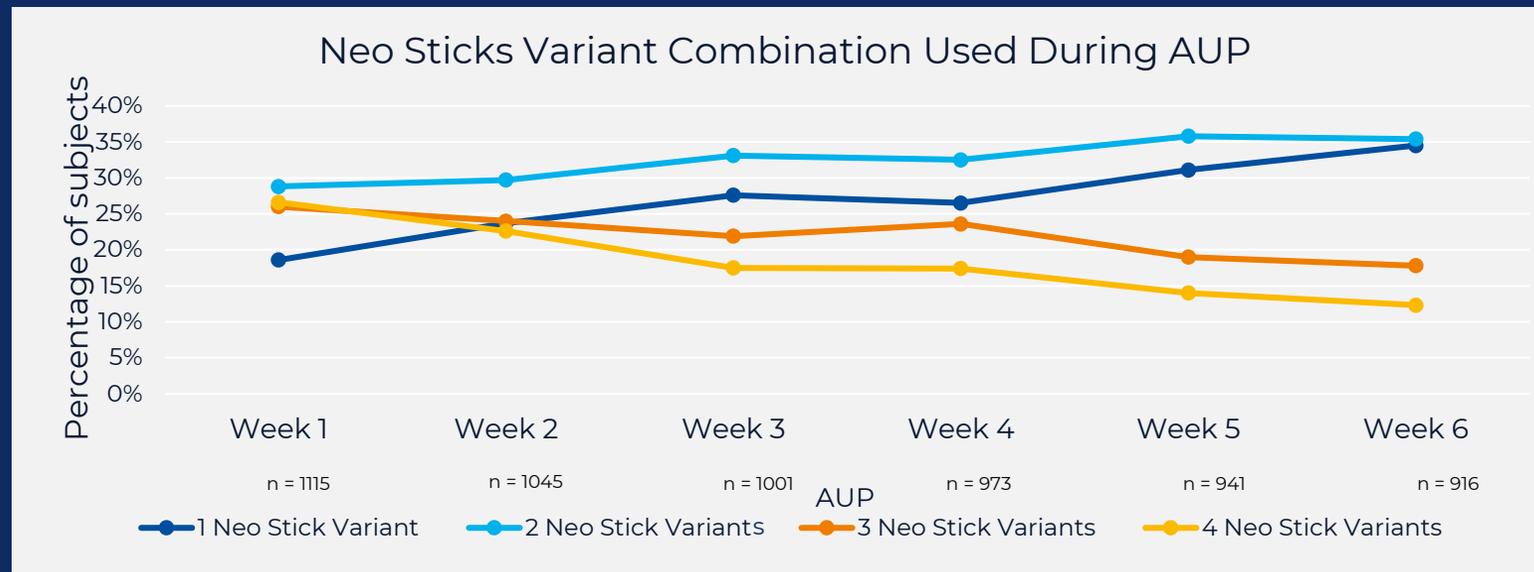
COMPLETELY QUIT CC

- ❑ 41 subjects (3.8%) reported to have completely quit CC at the end of the study
- ❑ 34 subjects (3.2%) were exclusively using glo™ at the end of the study

NEO STICK USE

NEO STICK USE

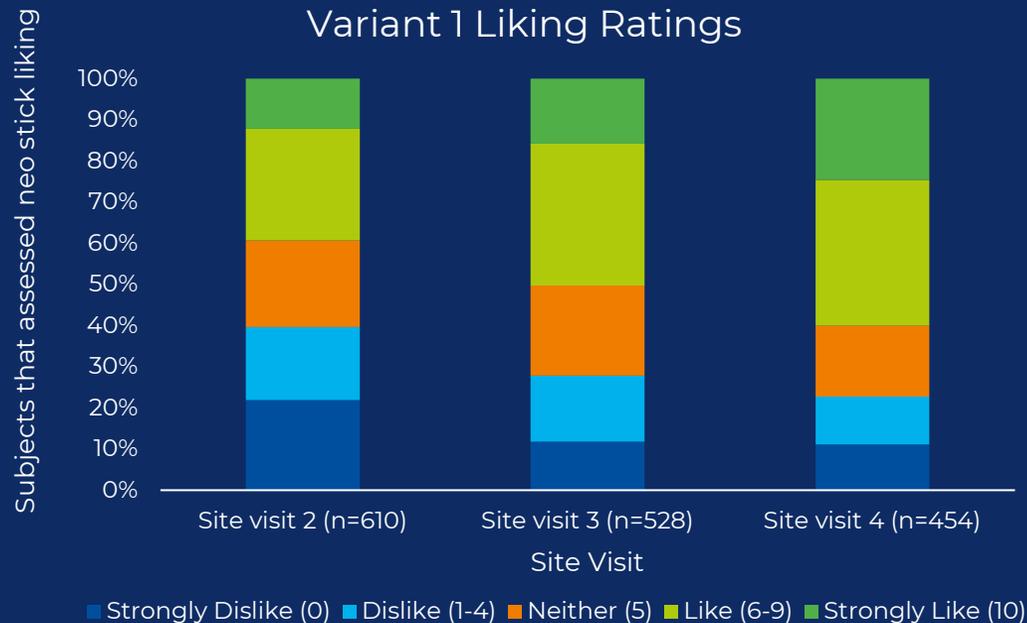
- By Week 6, the use of all 4 variants was evenly distributed
- By week 6, most subjects used 1 or 2 neo stick variants (compared to 2, 3 and 4 neo stick variants at week 1)



PRODUCT USE EXPERIENCE

NEO STICKS LIKING

- ❑ Liking rates increased over AUP
- ❑ Consistent across all four neo stick variant types



GLO™ MISUSE

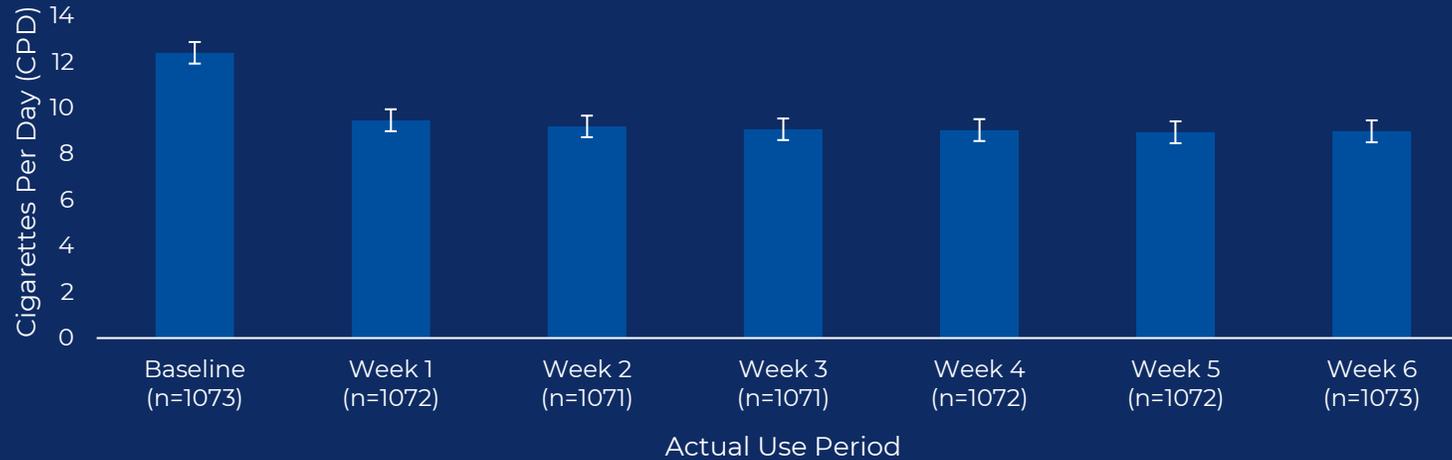
615 subjects reported using the product in a manner that differs from product use instructions

Most frequent glo™ Misuse:

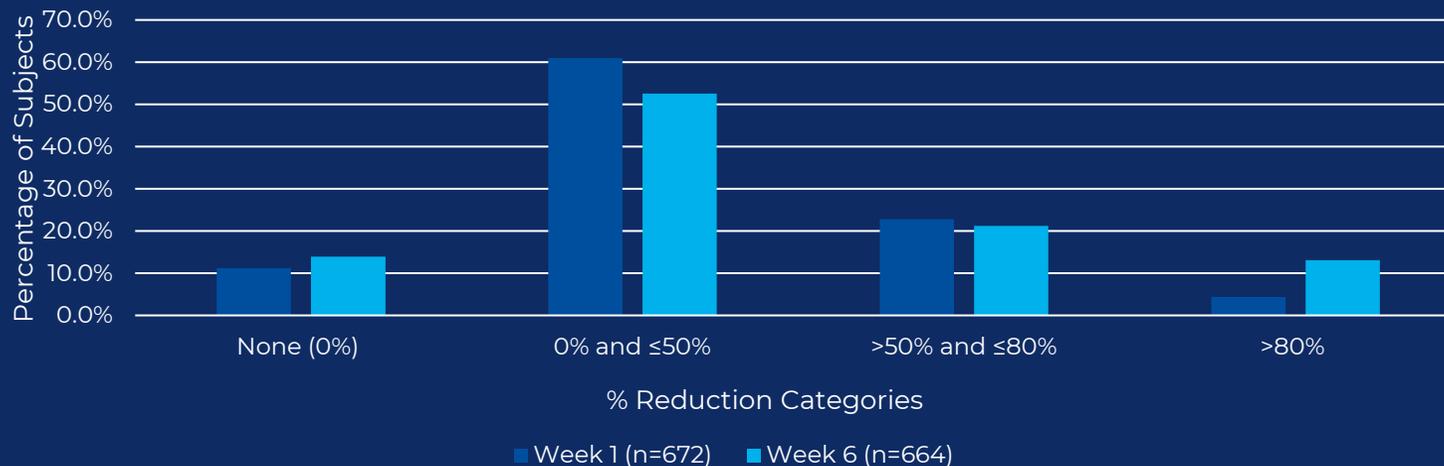
- ❑ Left glo unattended while charging
- ❑ Reuse of neo stick
- ❑ Tried to light and smoke a neo stick

CC CHANGE FROM BASELINE

CPD Over Time of all Study Completers



CC Reduction Over Time of Established Users



CIGARETTE USE CHANGE FROM BASELINE

All Study Completers

- Mean CPD decreased during AUP
- By Week 6 CPD reduction was 29%

All Completers & Established Users of glo™

- ~20% of all completers and **~14% of established users** did not reduce at all
- ~50% of all completers and **established users** reduced up to 50%
- ~24% of all completers and **~34% of established users** reduced more than 50%

Conclusions

- **61%** of participants **became established users** of glo™
- **35%** of established users **reduced their CC consumption** by $\geq 50\%$
- On **average**, CC consumption was **reduced by 29%**
- neo stick variants were **rated highly** on the **liking scale**
- **High compliance** rates (eDiary completion and site visit rates)
- **Low attrition** rate (4%)
- **Low AEs** reported (<1% subjects)
- glo™ has the potential to **positively impact public health**
- Study results have informed the **acceptance of glo™** and **CC consumption patterns**



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Thank you. Any Questions?