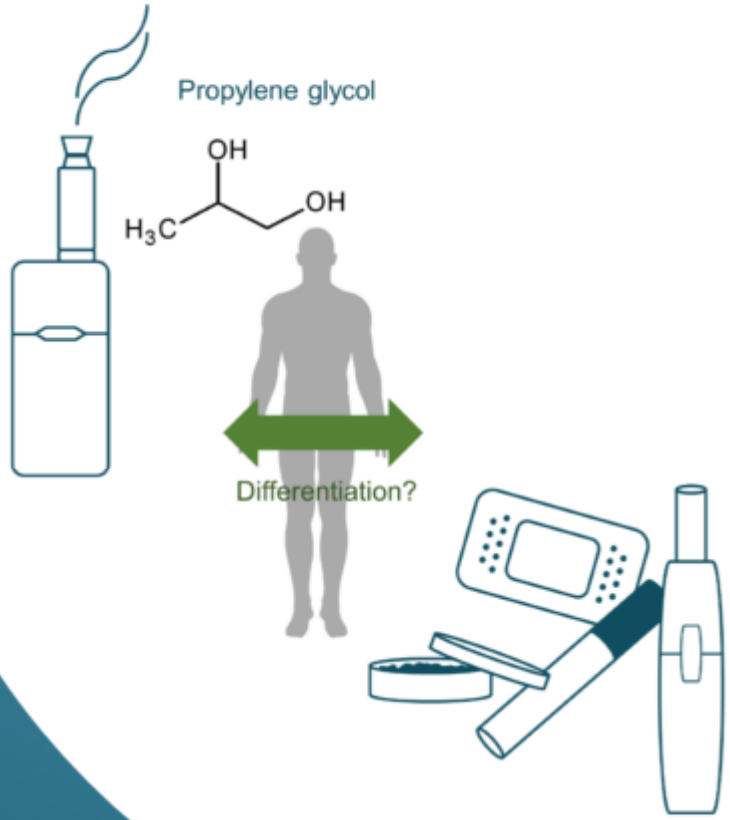
Determination of propylene glycol and glycerol in plasma and urine

Exposure assessment in e-cigarette users compared to other nicotine product user groups



T. Burkhardt, M. Scherer, G. Scherer, N. Pluym

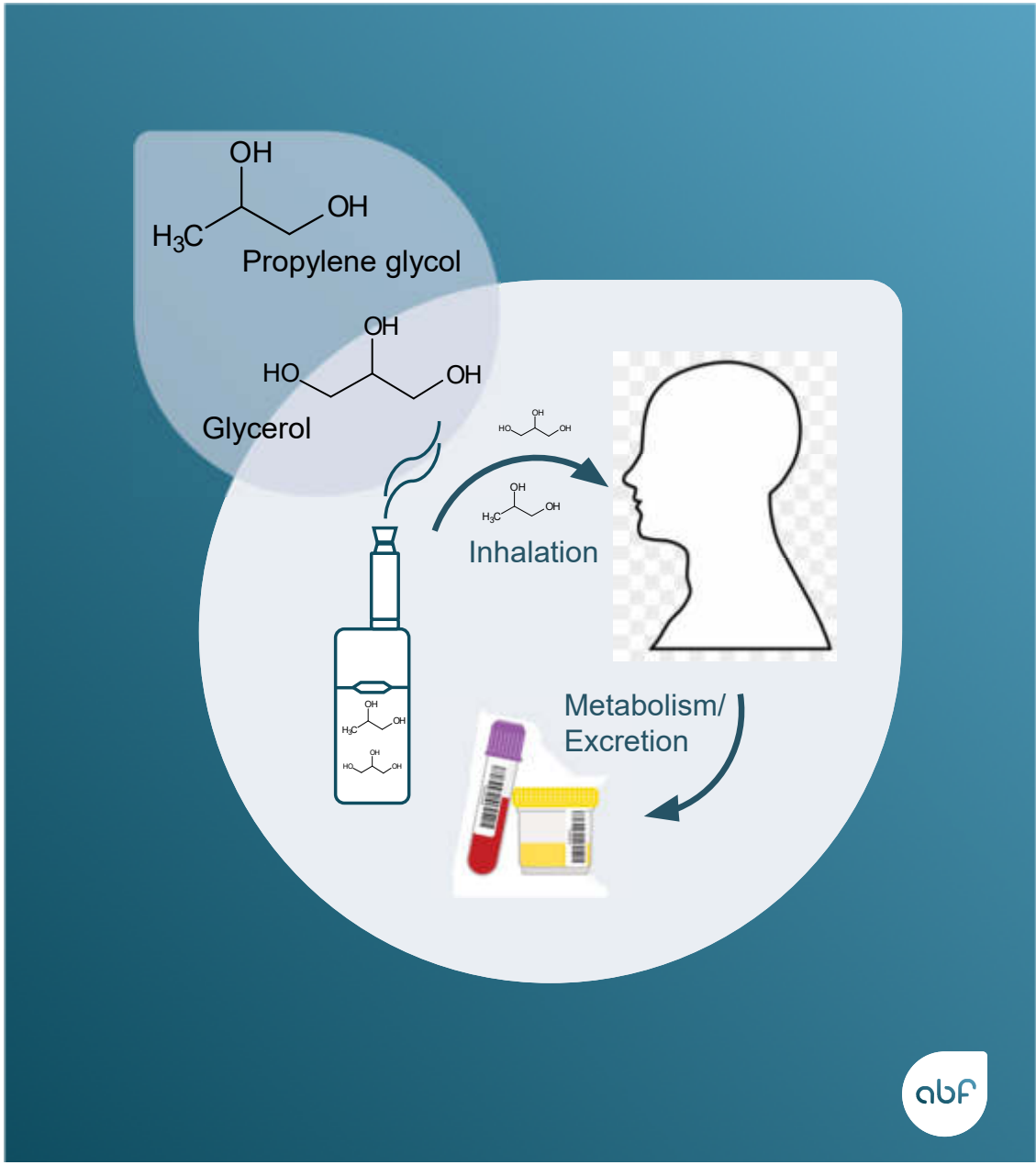
Analytisch-Biologisches Forschungslabor GmbH, Semmelweisstr. 5, 82152 Planegg, Germany

Propylene glycol and glycerol

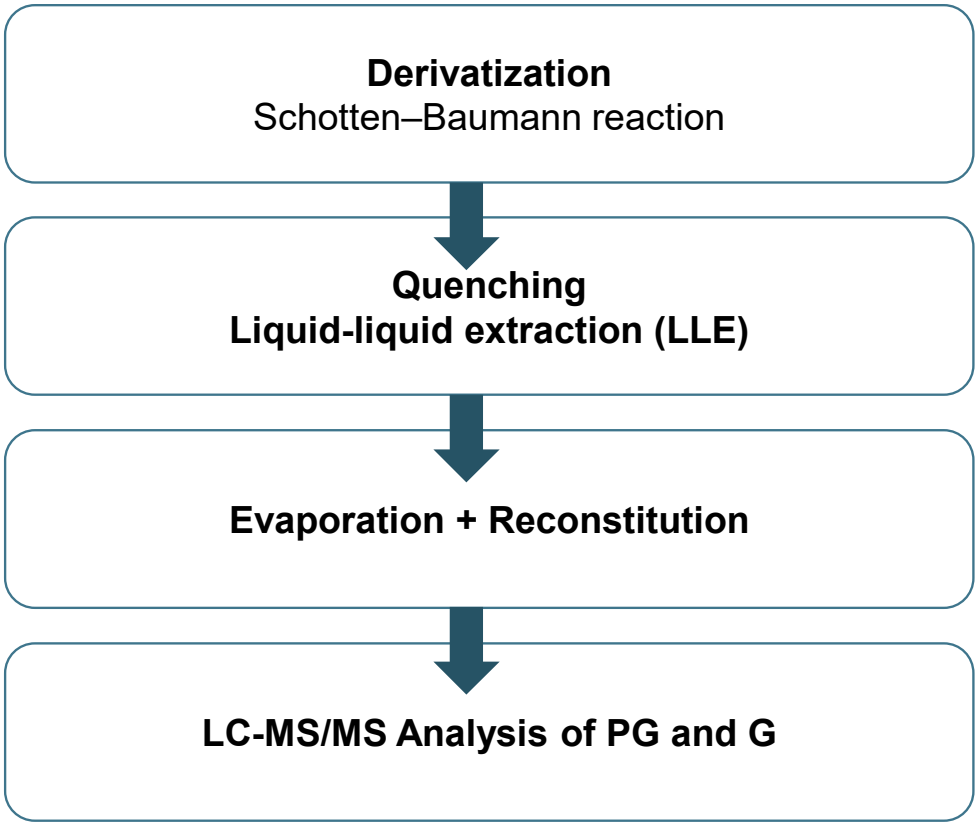
- Propylene glycol (PG) and glycerol (G) are the main e-liquid constituents
- By vaporization of the e-liquid, an aerosol containing PG and G in addition to other constituents such as nicotine and flavor chemicals is generated and inhaled
- Absorption, metabolism and excretion of PG and G

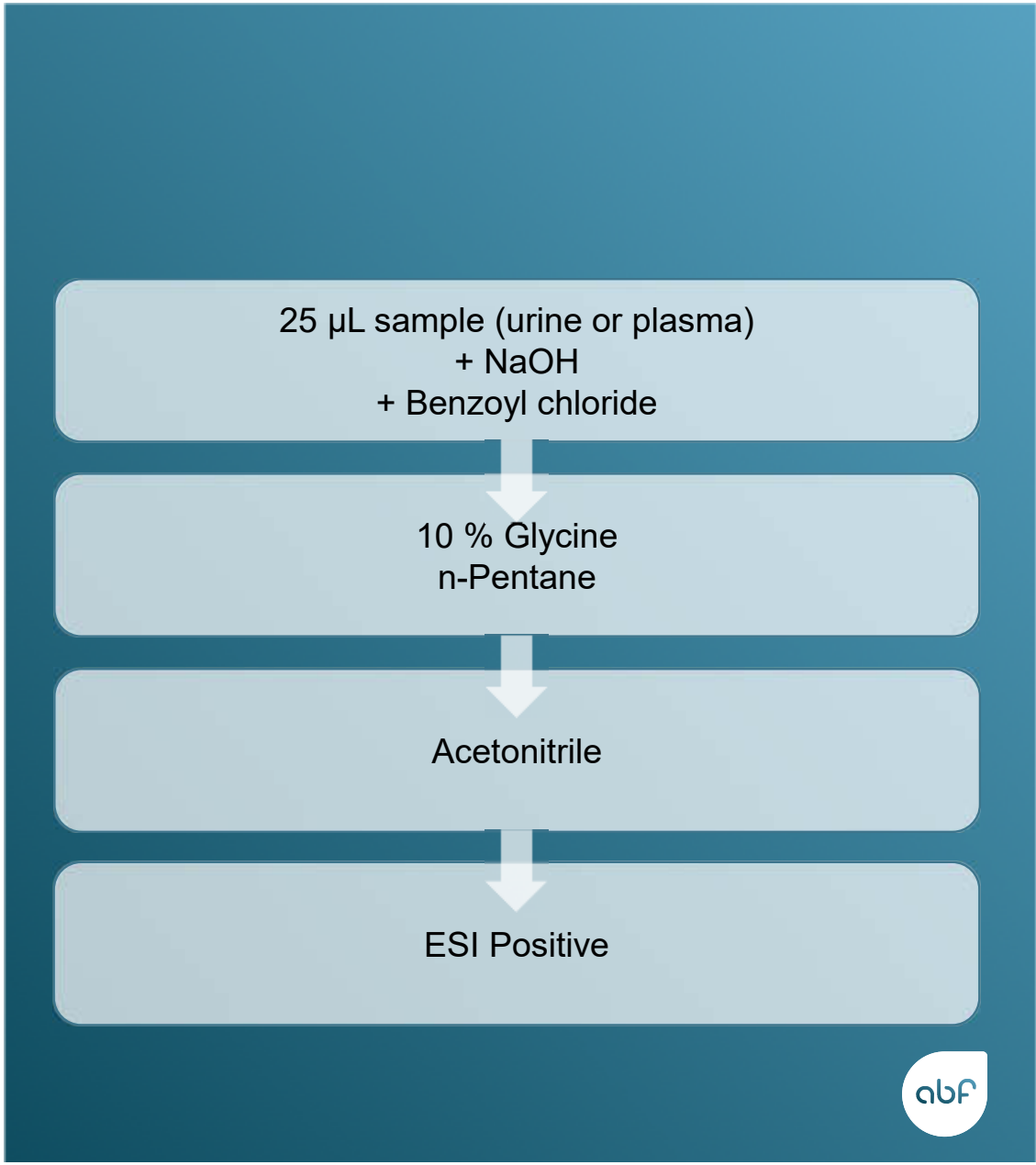
Hypothesis

Determination of PG and G in urine and plasma to differentiate between e-cigarette and other nicotine product users as well as non-users



Quantification of propylene glycol and glycerol by LC-MS/MS





Clinical Study – Study Design

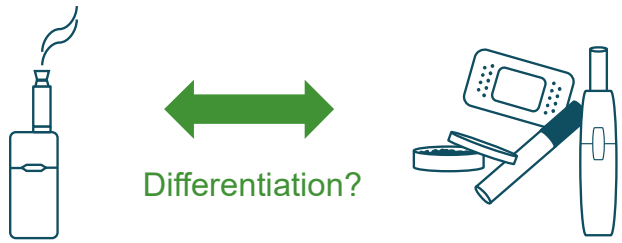
Clinical Study with 5 different nicotine product user groups and a non-user group (control)

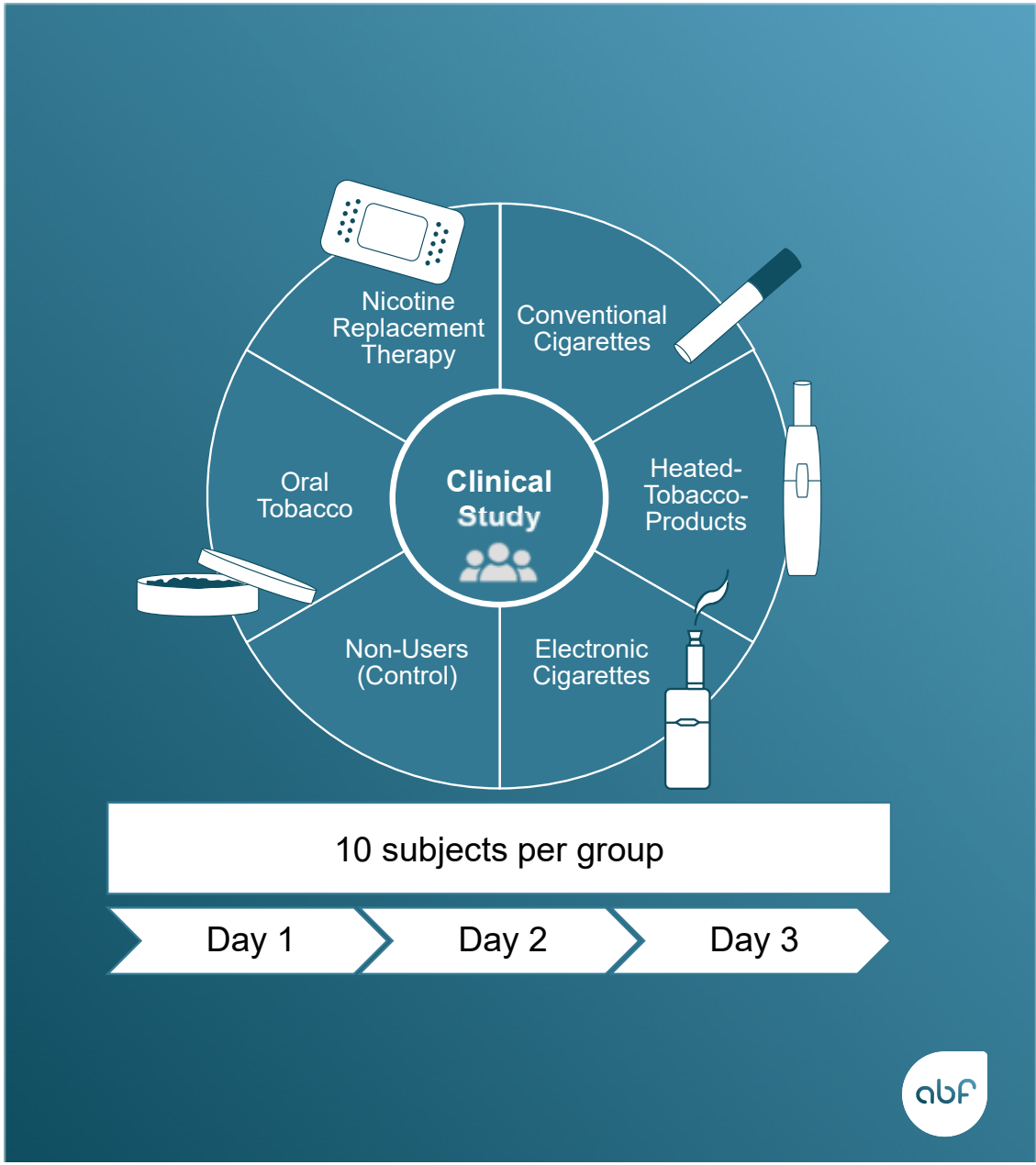
General study objective

Identify biomarkers or biomarker patterns capable to discriminate between different nicotine product user groups and non-users.

Specific objective of PG and G analysis

Quantification of PG and G in urine and plasma samples in order to **differentiate** between **e-cigarette users** and other nicotine product user groups and non-users.

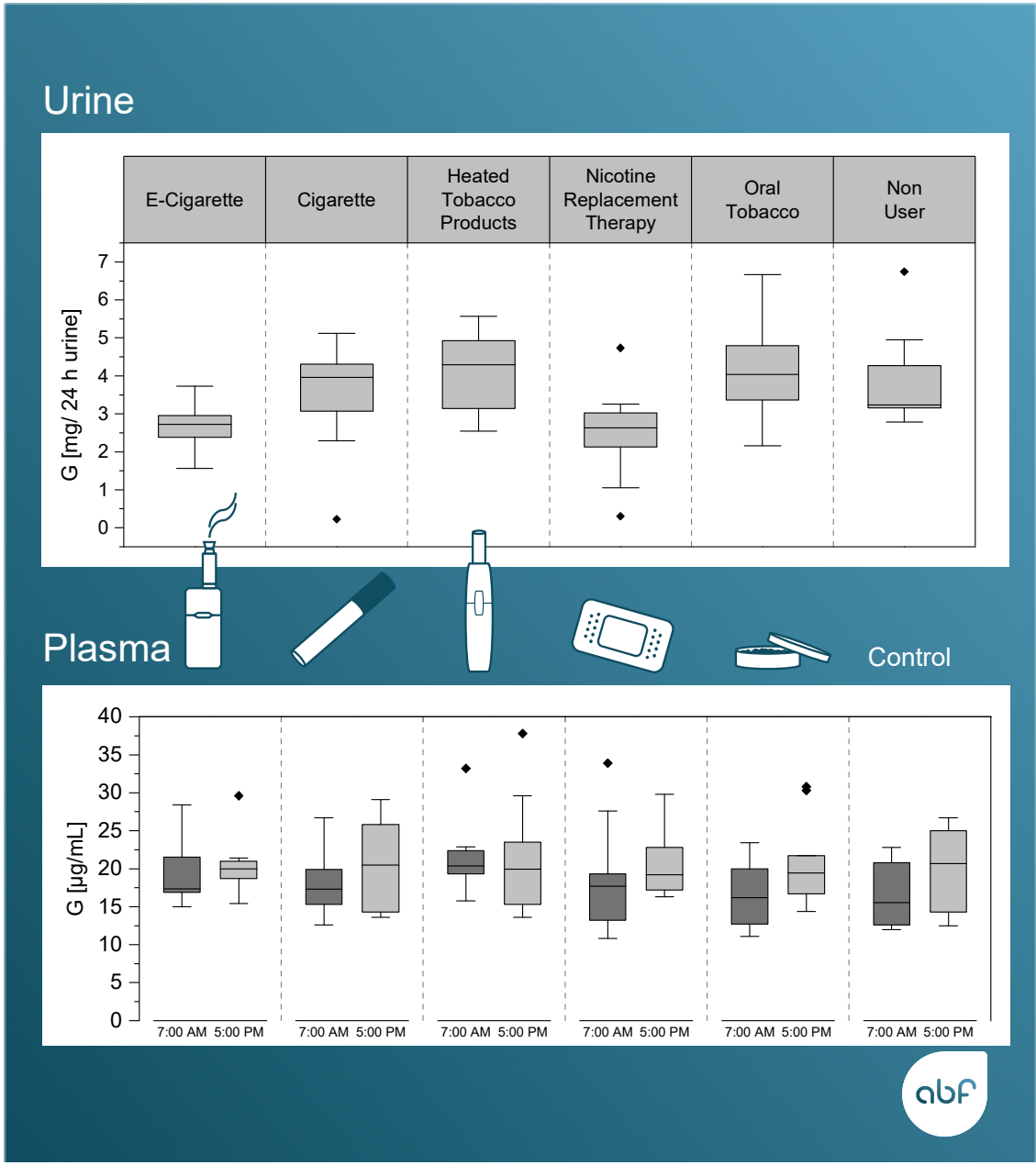




Results of G analysis in **urine** and **plasma**

- **Urine: NO significant differences** in G content of **e-cigarette** users compared to other nicotine product user groups and non-users ($p > 0.01$, Mann-Whitney U Test, 24 h urine)
- **Plasma: NO significant differences** in G content of **e-cigarette** users compared to other nicotine product user groups and non-users ($p > 0.01$, Mann-Whitney U Test, day 3)

Glycerol is **no suitable biomarker** to differentiate between **e-cigarette users** and other **nicotine product user groups and non-users**

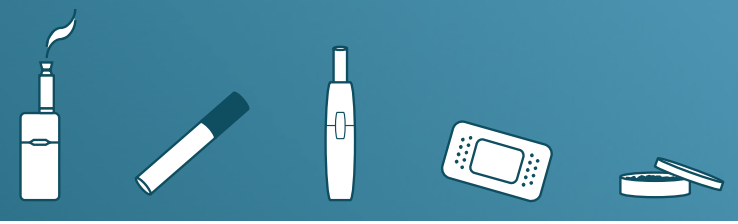


Results of PG analysis in **urine**

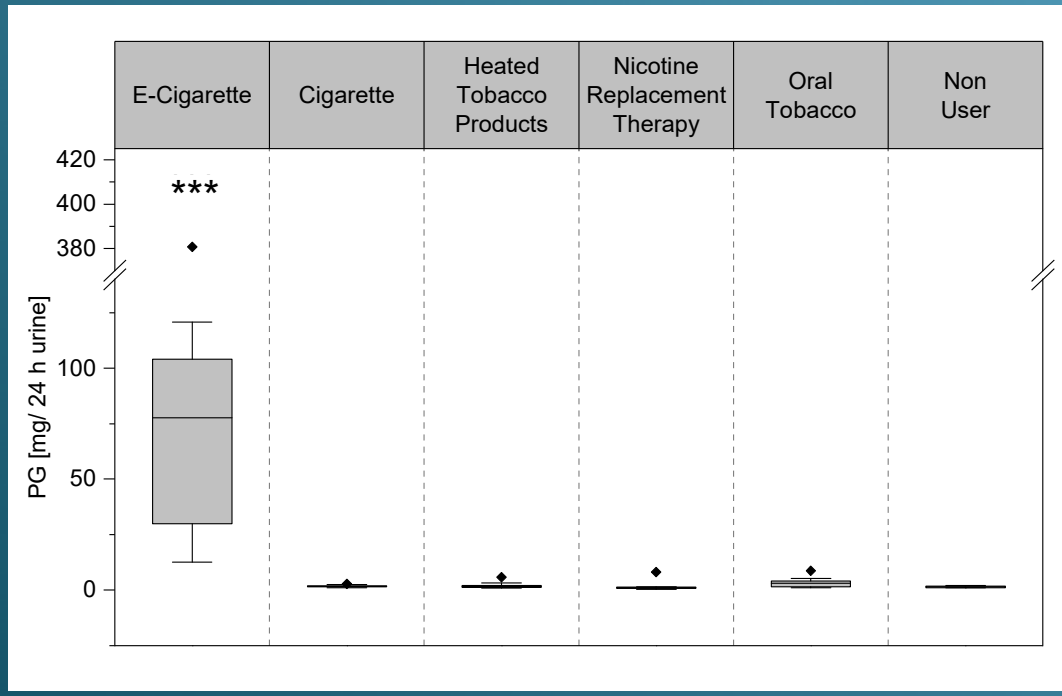


- **Significant differences** in PG excretion of **e-cigarette** users compared to other nicotine product user groups and non-users ($p < 0.001$, Mann-Whitney U Test, 24 h urine)

Differentiation between **e-cigarette users** and other **nicotine user groups** based on PG content in urine possible



Control



Results of PG analysis in **urine**

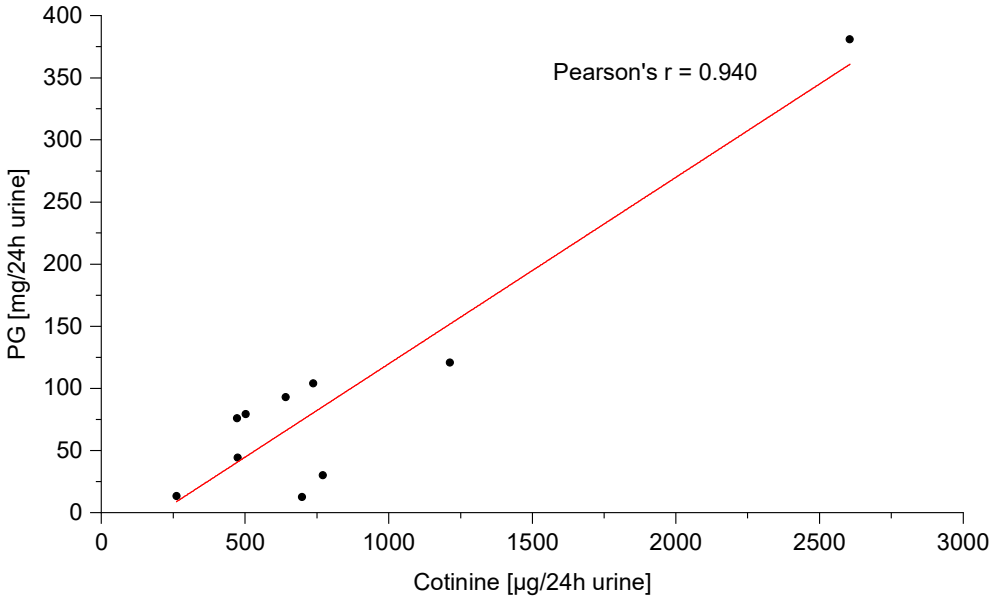


- PG uptake depends on vaping behavior

  Influencing factors: composition of the liquid (PG content), e-cigarette device characteristics (model, wattage, temperature), use behavior (puff number, puff duration, etc.)

- **Significant correlation** between **cotinine** (nicotine exposure) and **PG** in 24 h urine (Pearson's r = 0.940, day 3, $p < 0.01$)

Correlation between **E-cigarette consumption** and **PG level** in urine

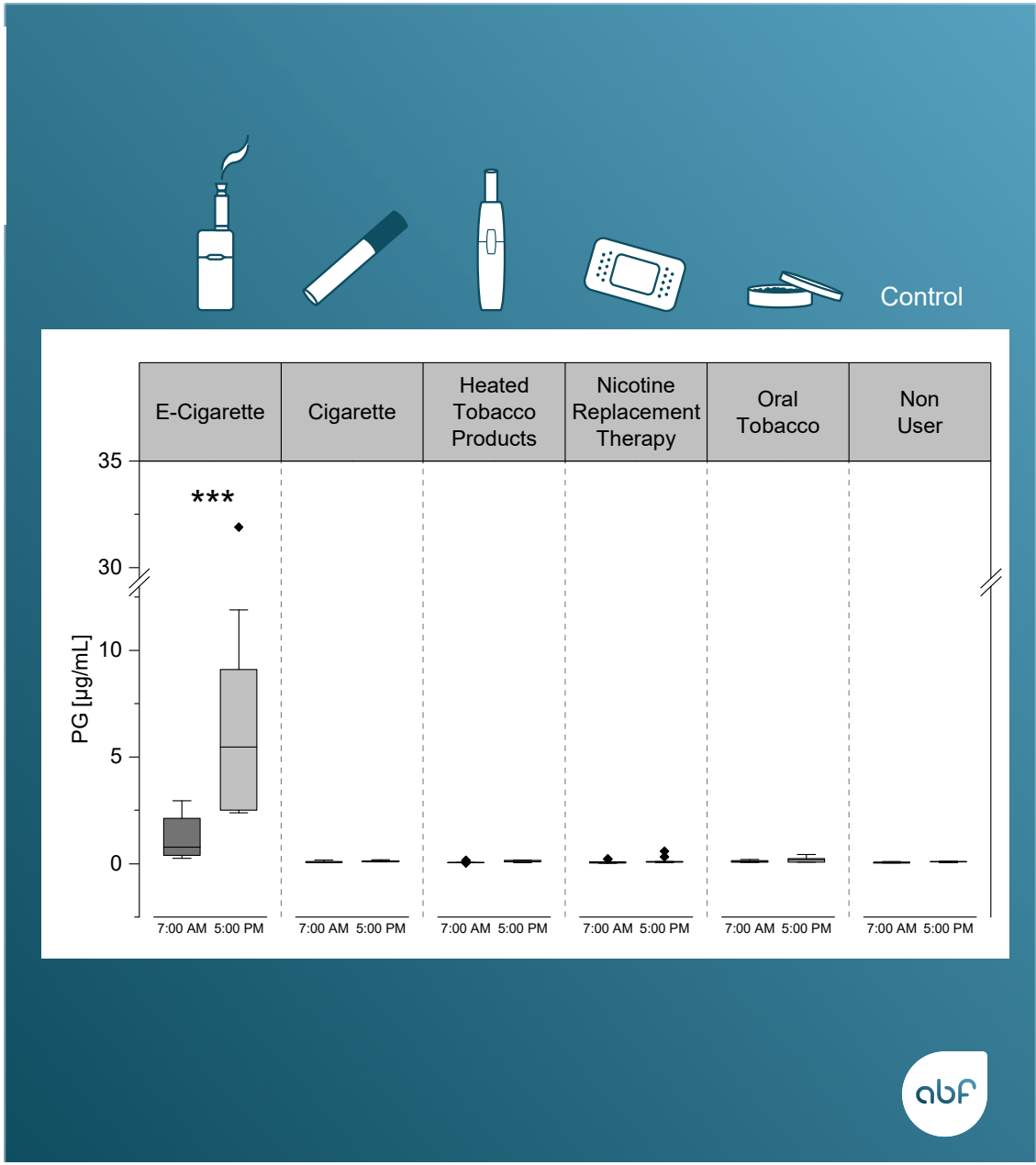


Results of PG analysis in **plasma**



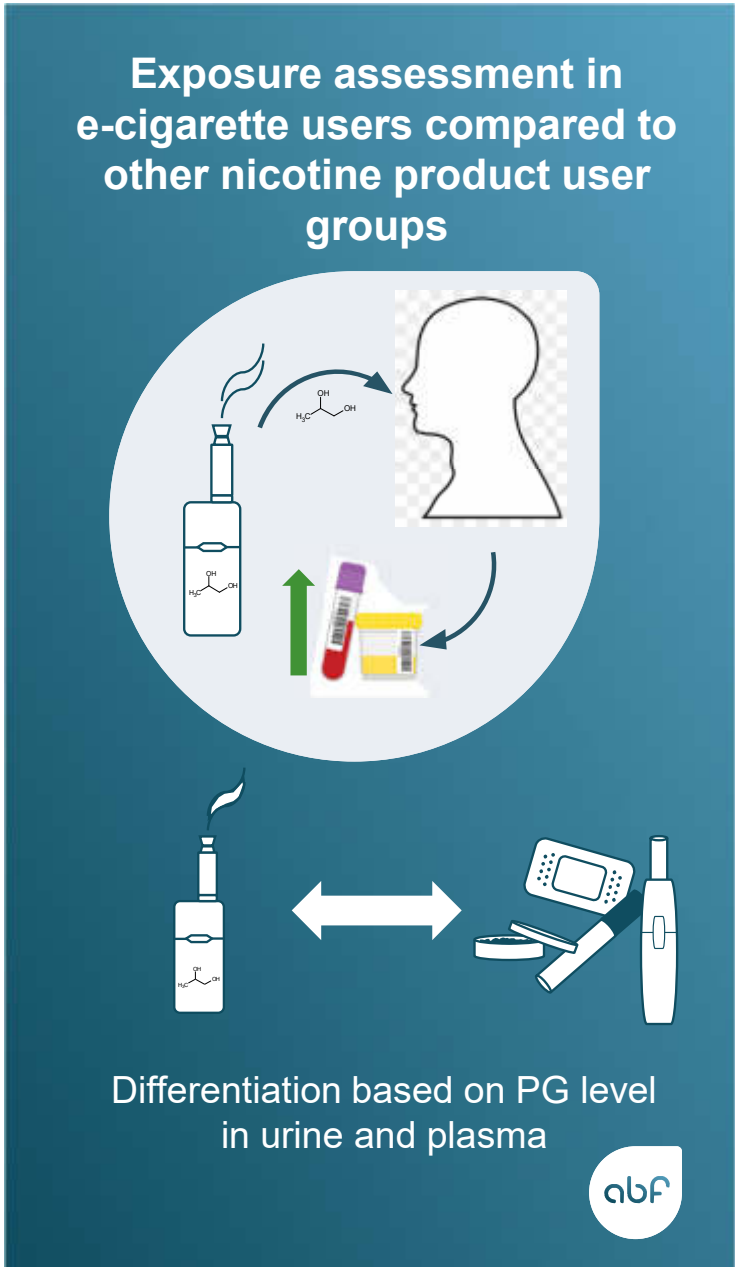
- **Significant differences** in PG content of **e-cigarette** users compared to other nicotine product user groups and non-users ($p < 0.001$, Mann-Whitney U test, plasma day 3)
- Increase in PG plasma concentrations during the day in correlation to e-cigarette use (no use before 8 AM)

Differentiation between **e-cigarette users** and other **nicotine product user groups** based on the PG content in plasma



Conclusion

- Development of a sensitive LC-MS/MS method for the determination of PG and G in urine and plasma
- **Glycerol NOT suitable** to differentiate between **e-cigarette** users and other nicotine user groups and non-users
- Significant differences in PG levels (in urine and plasma) of e-cigarette users compared to other nicotine product user groups and non-users
- PG excretion in urine strongly correlated to vaping behavior
- **Propylene glycol SUITABLE biomarker** to differentiate **e-cigarette** users from other nicotine product user groups including smokers as well as non-users



Acknowledgment

This study was funded with a grant from the **Foundation for a Smoke-Free World**, a US nonprofit 501(c)(3) private foundation with a mission to end smoking in this generation. The Foundation accepts charitable gifts from PMI Global Services Inc. (PMI); under the Foundation's Bylaws and Pledge Agreement with PMI, the Foundation is independent from PMI and the tobacco industry. The contents, selection, and presentation of facts, as well as any opinions expressed herein are the sole responsibility of the authors and under no circumstances shall be regarded as reflecting the positions of the Foundation for a Smoke-Free World, Inc.

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