



# ***In Vitro* Toxicity Testing (IVT) Sub-Group Report**

**Virtual Smoke-Techno Conference (SSPT2021)**

**October 2021**



## ❖ **Sub-Group Composition**

- Coordinator : Damian McHugh (Philip Morris International)
- Secretary : Liam Simms (Imperial Brands)

## ❖ **Current Objectives**

1. To compile and review information on *in vitro* toxicity testing and apply learnings to further biological research.
2. To organise and conduct periodically proficiency testing of tobacco and tobacco related products.
3. To identify and assess trapping methods supporting *in vitro* ENDS aerosol safety assessments



# « IVT SG » Achievements

## ❖ Achievements

| Project No. | Project Name: Activity                           | Leader      | Status   |
|-------------|--|-------------|----------|
| 245         | CTR-Ames test                                    | R. Wiczorek | Finished |
| 286         | CXP- Whole smoke Testing Methodology Publication | D.Thorne    | Finished |

## ❖ Priorities

- Support the assessment of novel tobacco products (ENDS) with robust data and studies on trapping methodologies to support regulatory toxicity testing.
- Perform in vitro proficiency studies to support CORESTA member accredited laboratories.
- Working successfully with the IIVS ("Institute for In Vitro Sciences") to share and discuss our results in a Workshop environment.



## ❖ Workstreams:

- **ENDS testing recommendations : U.Doshi (ALCS) and A. Irene (JTI)**
  - Part 1 focus on e-liquid. Recommendations to be put forward by the end of Q3.
  - Ames, NRU, in vitro Micronucleus, and alternative assays in scope
- ***In vitro* proficiency and ring trial studies: E. Weber (JTI) and R. Wieczorek (IB)**
  - Proposed time schedule: in vitro MN and NRU (2021), MLA (2022), and Ames (2023)
  - Candidates of the test pieces (TBD) : Kentucky Reference, Flue Cured, Burley, and e-liquid (PG/VG/nicotine ± mutagenic spike substance), and others
  - in vitro MN study ongoing – reporting Q2 2022.



# « IVT SG » Workstreams

- **E-Vapour and HTP aerosol trapping methodologies : E.T. Sticken (IB), D. Thorne (BAT), D. Smart (PMI), U.Doshi (ALCS), D. Thorne (BAT) and D. Smart (PMI)**
  - Scope is to identify and assess the performance, both chemically and toxicologically, of ENDS aerosol trapping technologies with the aim to have a set of CORESTA recommendations within the next 2 years. The work group will identify and prioritise the test pieces, trapping technologies and chemical markers which will be advanced to a feasibility study within the member labs.
- ***In vitro* test methodologies for novel tobacco products: T. Hashizume (JT) and J. Yao (JUUL)**
  - Information of proposed assays (ToxTracker, and Multiflow) shared. The group to prepare summary table of proposed assays with the rest of the group for further discussion. Discussions ongoing with NGTX to ensure alignment of work.



# « IVT SG » Workstreams

- **Support for external workshop (IIVS Workshop): L. Simms (IB) and R. Leverette (RJRT)**
- **To ensure that the activities of both groups (CORESTA IVTSG and IIVS) are known, to prevent duplication of effort.**
  - IIVS Genotoxicity Workgroup: Led by Dr. Martha Moore, Hosted by IIVS
  - Several members of the IVTSG participate in the meetings
  - Manuscripts: Workshop Series to Identify, Discuss and Develop Recommendations for the Optimal Generation and Use of an In Vitro Assay Data for Tobacco Product Evaluation: Phase 1 Genotoxicity Assays, *Applied In Vitro Toxicology*, 6 (2). (<https://doi.org/10.1089/aivt.2020.0004>)
  - Manuscript: Collecting e-cigarette aerosols for in vitro applications: A survey of the biomedical literature and opportunities to increase the value of submerged cell culture-based assessments, *Journal of Applied Toxicology*, 41(1). (<https://doi.org/10.1002/jat.4064>).
  - Workshop #6 (virtual) scheduled for October 25 – 27, 2021 Focus on Dosimetry



# « IVT SG » Meetings

## ❖ Meetings

- Last: February 2021, Online
- Next: November 2021, Online