

Building Stakeholder Relationships to Facilitate Expanded Application of Non-Targeted Analysis Methods

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The views expressed in this presentation are those of the authors and do not necessarily reflect the views of policies of the US Environmental Protection Agency.



A consensus-based working group formed to address challenges in Non-Targeted Analysis studies using mass spectrometry

Chairs:

Christine Fisher (FDA) Ruth Marfil-Vega (Shimadzu)





Organization

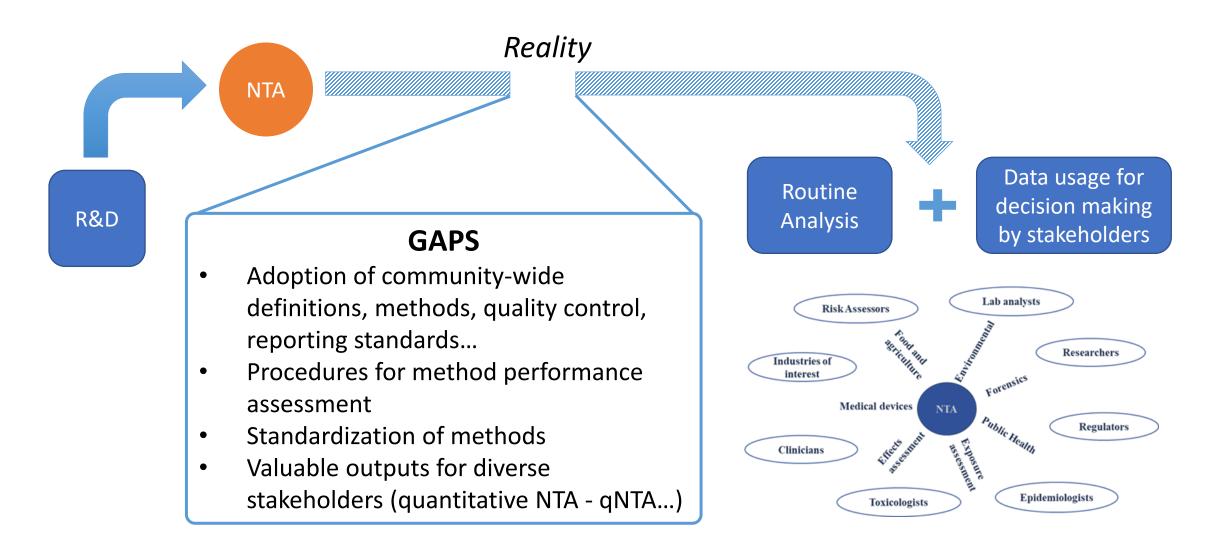


- >170 international members from government, industry and academia
- Organized into Sub-committees, with chairs from each group forming the Steering Committee
- Monthly meetings, alternating business discussions with presentations by Non-Targeted Analysis practitioners (including non-BP4NTA members)
- Join us the 3rd Tuesday of every month, at 12 pm EST (non-members welcome!)

Motivation

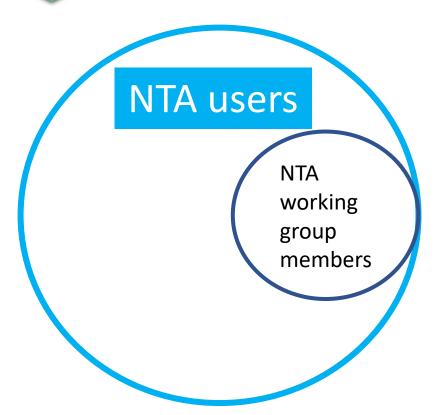
Ideal situation NTA Data usage for Routine decision making R&D Analysis by stakeholders Lab analysts Risk Assessors Researchers Industries of interest Medical devices Regulators Clinicians **Epidemiologists Toxicologists**

Motivation









Stakeholder Outreach

NTA users

NTA working group members

Non-NTA users who could benefit from NTA

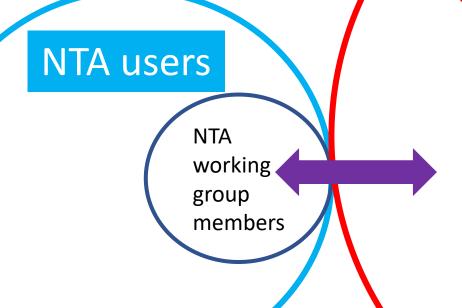
- Laboratory analysts
 - Government, industry, academic
- Risk Assessors
- Decision Makers
- Manufacturers
- Public

Stakeholder Outreach

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Stakeholder engagement





Stakeholder Subcommittee

- Engage with stakeholders who have limited to no involvement in R&D tasks related to NTA
 - e.g., regulators/decision makers, commercial labs, manufacturers of industrial and consumer products, utilities...
- 2. Identify common needs for implementing NTA among stakeholder groups to prioritize future BP4NTA efforts
- 3. Work together with stakeholders to create tools for facilitating implementation of NTA

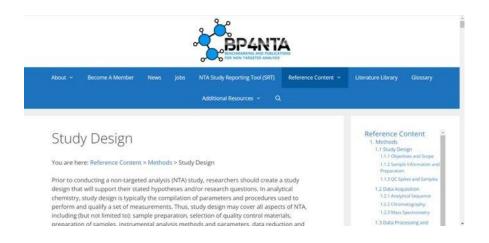
Engagement strategies

- Passive
 - Website
 - Videos
 - Fact sheets



Engagement strategies

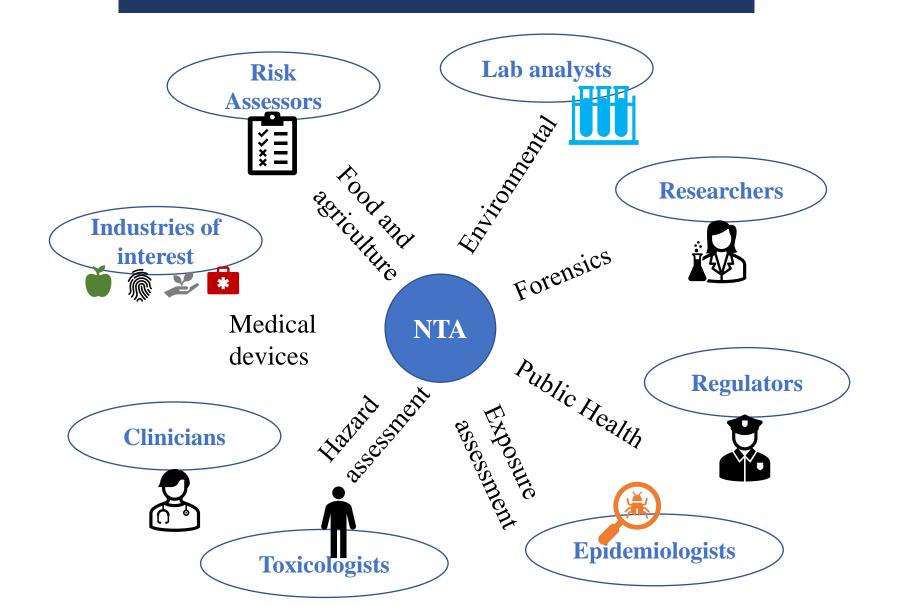
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 - Website
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- Active
 - Informal conversation
 - Meetings
 - Workshops



Stakeholder Identification



Meeting 1: Food and Agriculture Lab Analysts

- Attendee profile (6 stakeholder attendees):
 - Government lab analysts with HRMS experience
 - Most were US state employees
 - Work under ISO 17025 Accreditation
 - Use "screening" strategies in current work, but not full adoption of NTA
- Meeting goals:
 - Introduce BP4NTA and establish credibility
 - Listen to stakeholder opinions: reasons for using/not using NTA
 - Follow-up poll to collect additional thoughts and information



Discussion Questions



- Do you currently use NTA in your work? How?
- What do you see as the biggest opportunities for using NTA in your field?
- What are the biggest barriers inhibiting NTA use in your lab?
- What resources would be useful for incorporating more NTA in your work?
- Are you interested in participating in the creation/testing of these resources?



Findings: NTA Barriers

- Most regulatory analysis needs to remain targeted
 - Quantification is often necessary
 - Regulatory action almost always requires verification with a standard
 - NTA is useful for forensic/diagnostic work and for when standards are not available
- Current limitations on NTA:
 - Lack of ability to ensure data quality
 - Lack of high throughput data processing tools
 - Turn around time
 - Lack of understanding for end users of the data

Findings: NTA Opportunities

- All attendees were interested in doing more NTA
- Topics of future interest
 - Method performance assessment
 - Performance evaluation tools
 - Multi-lab validation studies and performance testing opportunities
 - Preference for methods that avoid false negatives
 - Quantitative NTA approaches
 - Retention time prediction
- Interest in NTA training opportunities at conferences
 - ASMS, AOAC, NACRW recommended



Lessons Learned

• The definition of NTA is debated!



• Even in a small group, it is difficult to get vocal input from everyone



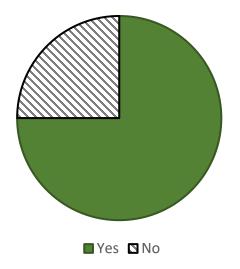
- Chat and follow-up poll were key for quieter participants
- A longer meeting time (2 h vs 1 h) might work better



Materials Developed

- Meeting summary shared with BP4NTA members
- Meeting preparation materials
 - Invitation email
 - BP4NTA introduction slides
 - Discussion question list

Are you interested in joining BP4NTA?



Meeting Plans in Progress:

Medical device regulators

Champion: Christine Fisher, US FDA

Rapid responders

 Champions: Alli Phillips, US EPA; Greg Johnson, University of North Carolina

Epidemiologist

Champion: Krystal Pollitt (Yale)

Risk Assessors

Champion: Yong-lai Feng (Health Canada)

• Others being considered: forensics, NGOs...



PFAS Stakeholders – Piggyback with EPA Efforts



October 2021 Virtual Conference:

Total PFAS Analysis for Public Health Protection: Science, Applications, Benefits and Challenges

- Audience: regional/state/local regulators and government laboratories
 - ~900 registered attendees
- Organizers: James McCord, Tim Buckley, Regina Poeske, Matt Small
- Poll data on current NTA use and future barriers
- Identification of vocal and interested stakeholders

Meeting Plans in Progress:

- Environmental stakeholders commercial labs and utilities
 - Champions:

Ruth Marfil-Vega, Shimadzu; Greg Johnson, University of North Carolina

Details TBD Interested in participating?

Broader activities affected by stakeholder input

- Planning of future BP4NTA activities
 - BP4NTA Standard Methods and Materials Committee
 - Choices of events for publicizing BP4NTA



Join us!



- Identify and engage with research, regulatory, and industry-based stakeholders
- Help organize stakeholder outreach meetings and events
- Create products to support outreach activities
- Identify needs and challenges for adoption of NTA workflows or use of NTA outcomes in stakeholder organizations



Fill out the "Become a Member" form at nontargetedanalysis.org

Acknowledgements



Health



BP4NTA stakeholder committee members:

Co-Chairs: Yong-lai Feng and Sara Nason

Jon Sobus Ruth Marfil-Vega **Krystal Pollitt** James McCord Stephane Bayen Jessica Daniel Christine Fisher Alli Phillips Greg Johnson Matthew Newmeyer Chung Yang John Sloop











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