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Highlights from the 5th meeting of the Nitrosamine Implementation Oversight Group (NIOG) industry partners (IP)

- The NIOG informed Industry stakeholders of the new approaches for setting acceptable intake (AI) limits for nitrosamines in medicines developed by EU authorities together with International partner authorities.
- The NIOG introduced the new Carcinogenic Potency Carcinogenic Approach and Enhanced Ames Test approaches that were published in Q&A on nitrosamines in human medicines.
- Industry stakeholders welcomed the newly developed approaches and discussed with NIOG the practical elements on the implementation.
- NIOG confirmed that further revisions to the guidance is currently being worked on as a result of the introduction of the new CPCA and EAT approaches, and an update will be provided in the near future.
- NIOG encouraged cooperation between industry stakeholders on sharing information, as possible, on in vivo and in vitro tests to support toxicological assessment of nitrosamines

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