NTP
National Toxicology Program

Systematic Review & Evidence Integration by OHAT: Next Steps

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Next Steps and Updates

- Evaluation of systemic review framework in case-studies
- Update on data warehousing and information management activities
- Develop framework for considering *in vitro* and high throughput screening data
- Re-visit “level of concern” framework

Evaluation of Systematic Review Framework in Case-Studies

- Track performance metrics:
  - Time to complete, e.g., weeks/months of different phases, staff hours
  - Consistency across evaluation team, e.g., data extraction, risk of bias, confidence ratings
- Ease of implementing, clarity of language, alternative ways to approach when needed
- Consider issues identified in public and interagency comments
- Public webinar to discuss lessons learned during case studies
- Complete case studies during next calendar year

Information Management Update: DRAGON

- Continue to use DistillerSR for screening but moving to different software tool for data extraction (DRAGON)
  - DistillerSR is proprietary, DRAGON is a free data extraction tool being developed by ICF International
- Facilitates harmonized data collection and public sharing of data
- DRAGON has modules for human and animal studies - *in vitro* module coming soon

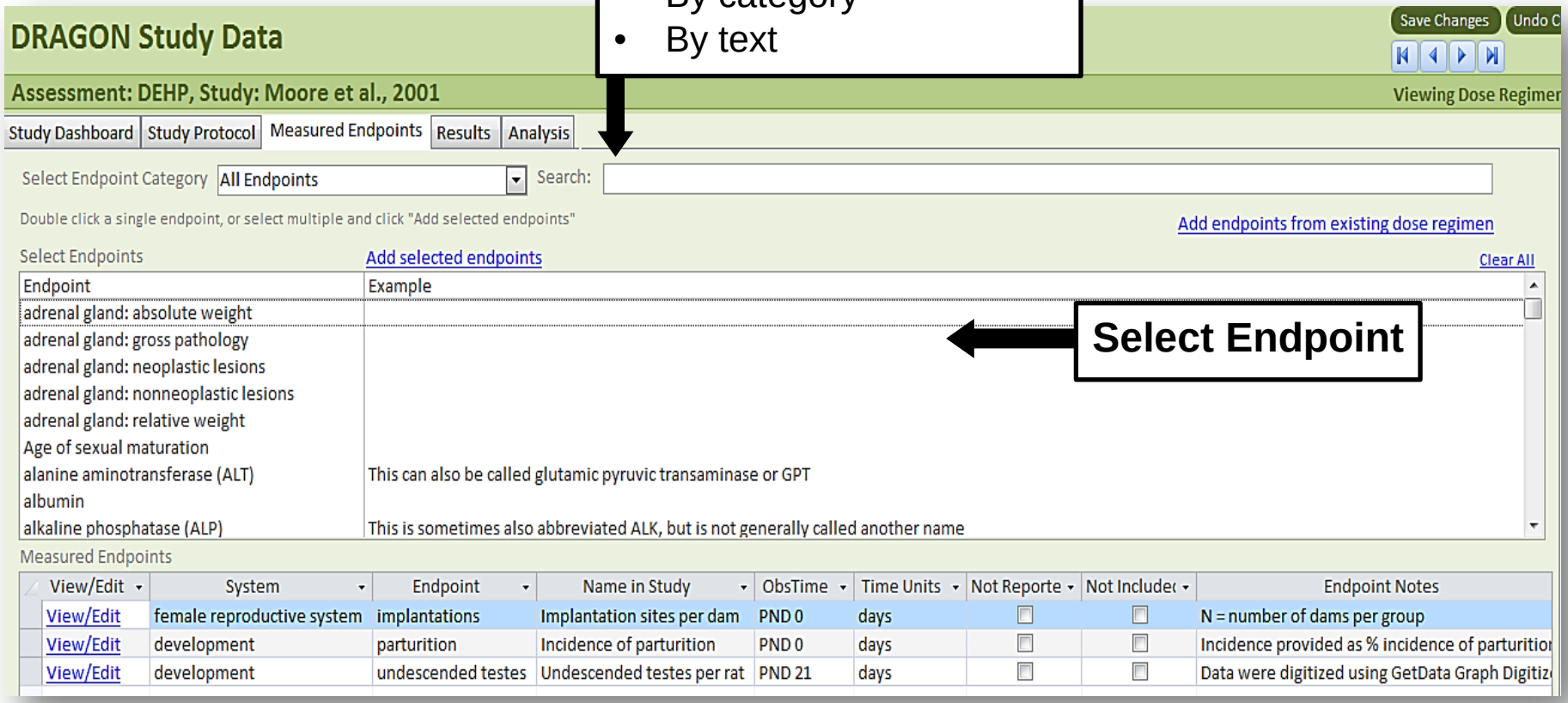
***ICF DRAGON Development Team**: Dr. Cara Henning, Kristen Marin, Josh Cleland, AJ Overton, Pam Ross, Audrey Turley

DRAGON Features

- Microsoft Access user interface, SQL backend
- Collection of extensive data extraction elements, including dose conversion tools
- Quality control workflow
- Ability to manage assignments and monitor progress
- Analysis modules
  - Benchmark dose for quantitative risk assessment
  - Statistical power assessment
  - Effect size conversion tools
- Create reports automatically e.g., appendix tables, evidence tables, Meta Data Viewer data files
- Multiple users can access at the same time

Promotes Common Vocabulary

Search for Endpoints
- By category
- By text



Select Endpoint

Add Details
- Name in study
- Notes
- View/Edit more

Framework for Considering *In Vitro* and High Throughput Screening (HTS) Data

- Framework for reaching confidence ratings and hazard identification
- Process
  - NTP-wide collaboration
  - Engage federal partners and other stakeholders
  - Public meetings
- Timeline
  - 2-3 years for initial draft framework
  - Framework will be “evergreen”

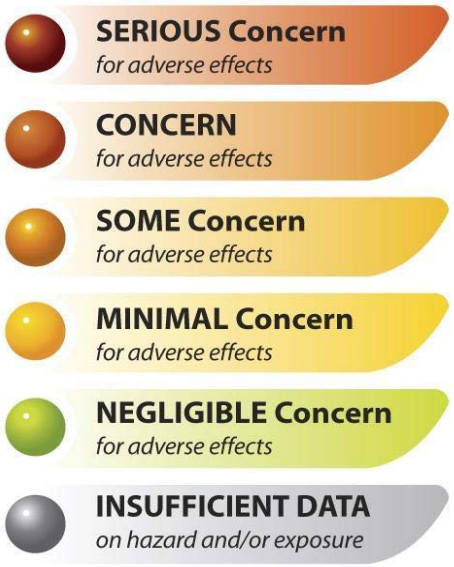
Re-Visit NTP Level of Concern Conclusions

- Formal NTP opinion based on an OHAT evaluation

Hazard ID label + **Extent of human exposure and other factors** = **Level of concern**

- Known
- Presumed
- Suspected
- Not classifiable

5 category scale + category for insufficient data



*May express different levels of concern for different health outcomes, age groups, or based on level or nature of exposure

Re-Visit NTP Level of Concern Conclusions

- Categories need better description
- Will remain narrative, i.e., not quantitative risk assessment
- Too many categories?
- Consider expressing confidence in level of concern conclusion?
- Gather input from technical advisors and focus groups
- Consideration of *in vitro* and HTS data