Formulation: **Day 1 Summary**

- Acceptability
  - Significant interest expressed in shared information platforms, but what data and structure still TBD. Context of how the data was generated is essential.
  - There is still work to be done on defining acceptability.
  - How do we advance the discussion on establishing criteria associated with acceptability
- Excipients
  - There definitely areas where development of novel excipients would be useful; however, unless there is an absolute need Sponsor's are unlikely to undertake development due to time constraints and associated risks.
  - Pharmaceutical companies hesitant to be first to use a new excipient. Has led to significant product development delays.
  - May be useful to establish a regulatory pathway for excipient manufactures to interact with regulatory agencies separate from drug product development.
  - Data sharing needs to be encouraged. IID should be updated to include daily use limits, patient population, and indication if feasible.
- Devices
  - There is interest in dosing devices for mini tablets and MPs, however there is concern about potential costs and regulatory hurdles; if dose banding is possible, the current preferred approaches appear to be stick/sachet packs or capsules.
  - A path forward may be for a collaboration to develop a "generic" mini tablet dosing device.
  - Concern regarding cleaning and re-use of oral dosing syringes.
  - There is a need for a global standard for oral syringes; Industry should work collaboratively with HCPs to define and implement appropriate specifications.
- Panel Session
  - Nomenclature… need to harmonize.
  - Data sharing, Carrot and Stick encouragement.
  - Considerable talk on excipient vs. active ingredient for bitter blockers.
  - Pharmahub.org – Excipient RA DB, are we using this?
  - Polypharmacy – Will platforms help integration across these therapies?

Formulation: **Day 1 Summary**

- Immediate thoughts on next steps…
  - Update IID to include daily use limits, patient population, indications for excipients.
  - Identify a path forward to encourage companies to share data. Carrot, stick, or both?
  - Can publication of data be incentivized or strongly encouraged?
  - Can Industry (through IQ?) take the lead on identifying what should go into an initial acceptability database, and just get started?
  - Can we establish a more discreet list of attributes for different dose forms to focus acceptability assessment on?
  - Can we create a collaborative or multi-stakeholder risk/benefit framework to help inform trade off decisions on acceptability?
    - EuPFI doing something similar on excipients – can we learn from this?

Analytical Summary: Day 1

Mini tablets:

Need harmonization/standardization on the following:

- Testing approaches for bulk vs. final product and single entity vs. combination products.
- Dissolution testing practices for sprinkles in capsules, similar to chewable tablets. (Comparison between final product and sprinkles and dispersed tablets
- Disintegration testing in lieu of dissolution
- Nomenclature for minitablet dosage form.

Next steps…

- White Paper on release strategies
- Guidance on disintegration and friability testing if enough information can be gathered.

Analytical Summary: Day 1

Dosing Vehicles:

- Starting points for vehicle selection:
  - Physiochemical properties of the drug (both compatibility/incompatibility, potential of foods to impact absorption)
  - taste of the drug
  - typical pediatric foods
  - Other important considerations: pH, patient population considerations, dosage form requirements, and geography.
- Generating compatibility data to identify usable food and to be included on label.
- Acceptance of different brands/regional differences could generate differences in performance. Most companies are testing single brand. Are thoughts aligned between industry and Regulators?

Thoughts for next steps:

- Standardized approach for vehicle selection. i.e. toolbox to assess the biggest risks with regard to chemical stability and compatibility, possibly through the use of chemical mixtures as a surrogate for food types
  - Alignment between FDA and EMA/PDCO on vehicles list.
  - A paper on dosing vehicles assessment based upon scientific justification – i.e. using a science based/risk based rationale
  - Establishing an agreement of validation practices for methods for analysis of product in dosing vehicles for in-use stability.