Improving Generic Drugs and Streamlining Their Approval through AI

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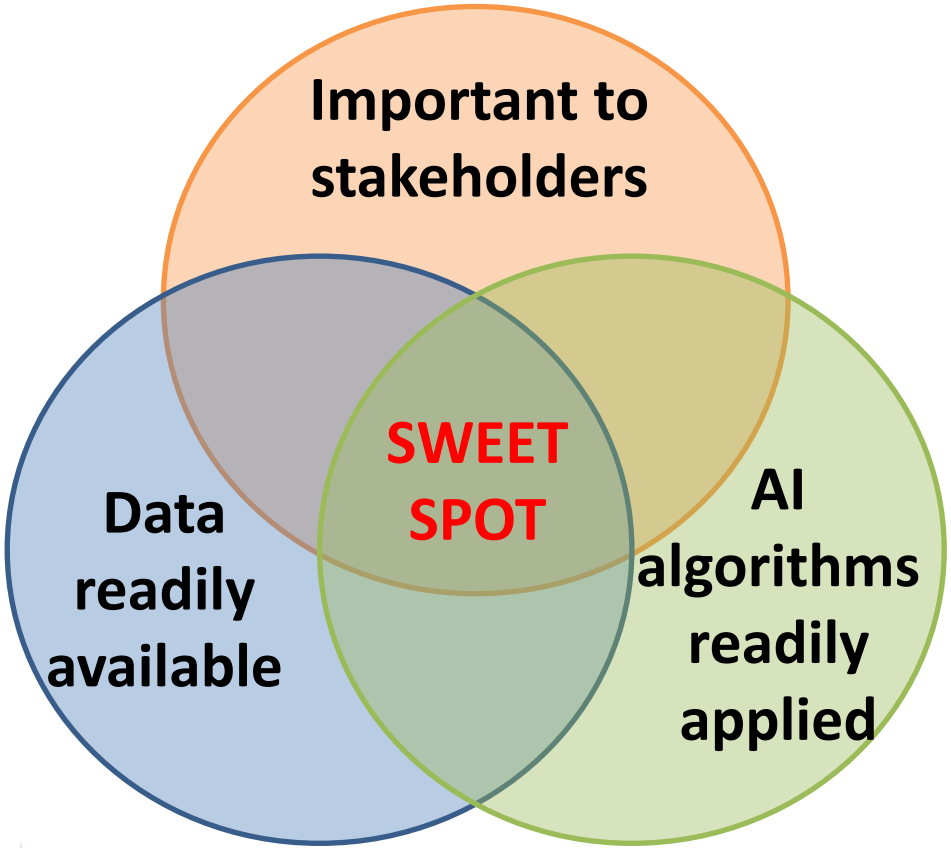
Which generic AI opportunities to pursue?



More than just about technical issues....

Implementation also counts!

Modes of use

- Inform/guide human decision-making
  - Humans will still make ultimate decisions
  - Easier to implement
- Direct AI decision-making
  - Significant rules and validation will be needed
  - Potentially useful for avoiding human biases
  - Harder to implement

Develop regulatory framework for AI

- Critical, especially for AI decision-making applications
- Issue guidances for:
  - Acceptable AI algorithms and their validation
  - Training/test data and performance criteria
- Need clear ruling from FDA legal counsel on use of other sponsors' data for AI purposes to avoid "takings" issues
- Learn from prior AI implementation in other regulated industries

Important near-term opportunities

- Evaluate pharmacokinetic (PK) and *In Vitro* Permeation Testing (IVPT) outliers
- Improve dermatological scoring methods
- Improve clinical endpoint BE study design
- Develop better PK timing metrics to replace pAUC
- Assess PK sampling adequacy

Important longer term opportunities

- Improve methods for comparing *in vitro* dissolution profiles
- Improve *in vitro* tests/acceptance criteria for inhalation products
- Re-evaluate current FDA rules on formulation similarity
- Resolve Inactive Ingredient Database (IID) issues
- AI-based FDA reviewer “assistant” (super-indexing)
- Unbiased post-marketing surveillance
- Unbiased reassessment of human study data *post hoc*

Challenges

- AI systems constantly learn, but regulatory frameworks need stable, predictable decision-making
- AI decision-making not be fully understandable, but regulatory framework demands clarity and transparency
  - May make stakeholders uncomfortable
  - Need effective public communication program
- Need guidances for implementing AI for regulated use
- Training set bias – data available to FDA mostly “passing”

Thank-you!

Scientists Advancing Affordable Medicines, Inc. (SAAMnow™) is a 501(c)(6) non-profit organization focused on bringing the best science to bear on the development and approval of affordable medicines, such as generics, 505(b)(2)s, and biosimilars.