

Proprietary modeling platforms to support regulatory interactions: A vendor's perspective

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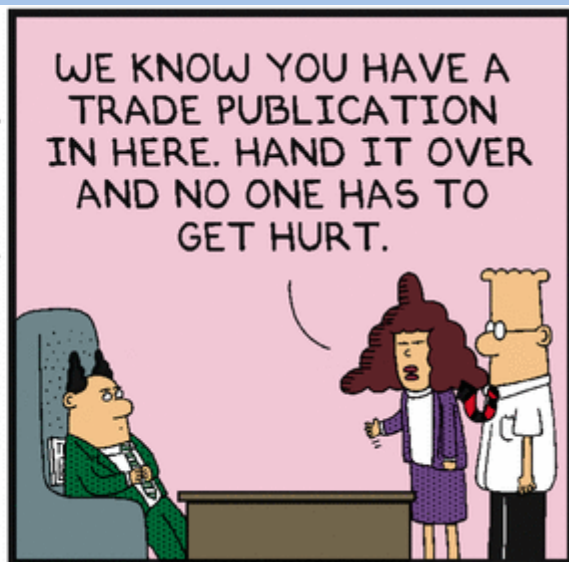


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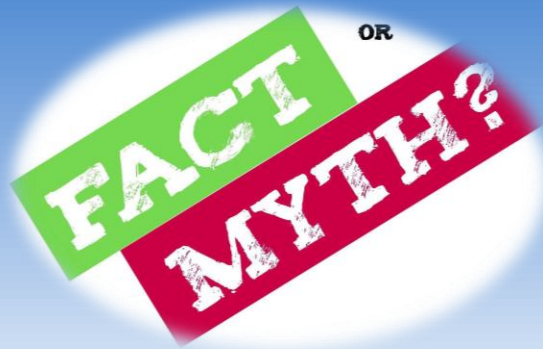
Why Are We Here Today?

- “The primary concern that prevents a regulatory agency from incorporating predictions generated from proprietary modeling platforms into their decision-making processes is the lack of open access to the platforms and underlying models and databases”
 - **NOT TRUE!**
- “Regulators, academics, or members of the general public may not be able to replicate the model predictions, or to evaluate the predictive capability of the model within a desired chemical space”
 - **NOT TRUE!**
- “Is access to all modeling platforms (source code) and databases used to generate model outputs required to verify the output?”
 - **NO!**
- “Is evaluation of a model by the platform developer sufficient to provide confidence in the outputs of a model?”
 - **YES!**

Proprietary Modeling Platforms – The Reality...

- Proprietary modeling platforms are:
 - **Driving the vast majority of internal R&D activities** at companies
 - >200 global customers for Simulations Plus; 100s more outsource modeling projects
 - **Integrated into 100s of university courses (for free)** to teach and train students
 - **Implementing significant (and consistent) innovation** driven through collaborations between commercial software vendors, companies, and government/academic groups
 - Examples include funded consortiums through IMI, Cosmetics Europe, and the FDA
 - **Accessed by trained regulatory scientists globally** to efficiently support filings/applications





- MYTH: 'Data' is hidden
 - ✓ FACT: Software is fully documented and referenced
 - ✓ Product manual is an open book – ALL equations & references available for review
 - ✓ FACT: ALL model variables (data) can be viewed/modified/saved in various formats (e.g., Access databases, Excel spreadsheets, ASCII text files)
- MYTH: Not available for everyone
 - ✓ FACT: Free teaching licenses available
 - ✓ FACT: Discounted (or free, if allowed) licenses for regulatory agencies
- MYTH: We don't know what it is doing
 - ✓ FACT: 1000s of peer-reviewed journal articles, scientific posters, and conference presentations showcase predictability for different applications

Suitability for Regulatory Support

- **Code/version/quality control**

- ✓ Strict SOPs when implementing 'Voice-of-Customer' selected functionality
- ✓ Feature/bug reports logged and assigned to different teams
- ✓ New versions and patches released annually

- **'Real world' implementation & compliance considerations**

- ✓ Consistent system validation procedures (to ensure compliance)
- ✓ Access privilege definitions (administrator, user, reviewer)
- ✓ Global support staff to address technical questions and train users

- **Platform qualification provides 'reproducibility confidence' to regulators**

- ✓ 1000s of peer-reviewed journal articles, scientific posters, and conference presentations showcase predictability for different applications
- ✓ No need for computer scientists on staff to review logic code, variable definitions, etc.



Why Are We Here Today?



- “The primary concern that arises from proprietary modeling is lack of access to the platforms and data”
– **NOT TRUE!**
- “Regulators, academics, or others are unable to replicate the model predictions, or to evaluate the model”
– **NOT TRUE!**
- “Is access to all modeling platform required to verify the output?”
– **NO!**
- “Is evaluation of a model by independent parties possible?”
– **YES!**

...incorporating predictions generated by modeling processes is the lack of open

...be able to replicate the model predictions within a desired chemical space”

...needed to generate model outputs

...provide confidence in the

**Are we creating problems that don't exist?
Let's work together to find logical solutions!**