MAPPING INVITRO DATA WITH CLINICAL OUTCOMES IN GENERIC DRUG DEVELOPMENT USING SIMBIOLOGY

Presented By: Parul Yadav
Aerodynamic simulations completed by computational fluid dynamics (CFD) experts over the last two decades were used to refine understandings of air loads on the SSLV and on thousands of protruding parts of the External Tank, Orbiter, and solid rocket boosters.*

Weather Research and Forecasting model output showing simulated radar reflectivity (dBZ) for Typhoon Mawar at 3.3-km (2.1-mi) grid spacing**.

*NASA@SC11 Demo: Space Shuttle Aerodynamics and Debris Simulations
**Weather Research and Forecasting Model - Wikipedia
SIMULATIONS IN HEALTHCARE

Predictive Data Analytics in Healthcare

Drug-Device Combination Development

1. 10 High-Value Use Cases for Predictive Analytics in Healthcare (healthitanalytics.com)
2. Cipla receives approval for Albuterol Sulfate Inhalation Aerosol (biospectrumindia.com)
Established in 1935, Cipla is a pioneer in the Indian pharmaceutical industry. Founded with a vision to make India self-reliant and self-sufficient in healthcare - Today, we have grown to become one of the world’s largest generic pharmaceutical companies with an aim to augment the affordability and access of global health care.

- 3rd largest in India¹
- 3rd largest in South Africa²
- Among the most dispensed generic companies in US³
- One of the world’s Largest Inhalation portfolios
- One of the world’s largest suppliers of anti-malarials
- 1 in 3 HIV patients take Cipla ARVs
- Markets – 80+
- Revenue – 17,132 crore

¹. IQVIA MAT Sep ’20 | 2. As per IQVIA MAT Sep’20 | 3. As per IMS MAT | 4. Based on combined sales in the generic accessible market
Cipla ranks **#2** in the sale of inhalers globally (by volume)

With presence in over **50** countries, Respiratory contributes **22%+** of total revenues.

Cipla’s Fluticasone Salmeterol brand holds **1st** position in terms of market share by volume in FPSM market in... Morocco

Foracort brand stood at **#10** among the 4 Cipla brands that featured in the top 50 brands of Indian Pharma Market

**46%** share of volume in MDIs in South Africa respiratory market

**Synchrobreathe**, a state-of-the-art innovative breath-actuated inhaler, helping millions with **Obstructive Airway Diseases such as asthma**.
INITIAL EXPLORATION

• In Vitro Data

• Clinical Outcomes

• Pharmacokinetic Modelling

Save Time and Cost
GENERIC DRUG DEVELOPMENT USING SIMBIOLOGY

- The model was validated against the literature data adequately and was verified against a challenge case designed using in-house formulation developed.
- The model accuracy is 95% and more for oral inhalation and has specificity of more than 80%.
- The model enables early decision making in the planning of clinical trials, screening multiple formulations and drug delivery optimisation.

### Model Input Parameters

- **Drug specific Physico-chemical properties**
- **Human pulmonary physiology and parameters of delivery mechanism**
- **In-vitro data of delivered Fluticasone Propionate**

### Batch ID

<table>
<thead>
<tr>
<th>Batch ID</th>
<th>Predicted PK</th>
<th>Actual PK</th>
<th>Accuracy (%)</th>
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<tbody>
<tr>
<td>FP-10011</td>
<td>61.35</td>
<td>59.84</td>
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<tr>
<td>FP-10012</td>
<td>64.30</td>
<td>66.75</td>
<td>96.3</td>
</tr>
</tbody>
</table>

**Predicted Pharmacokinetic Profiles**

![Graph showing predicted pharmacokinetic profiles for batches FP-10011 and FP-10012.](image)