Regulatory innovations to achieve vaccine development in 100-days

Adam Hacker, PhD
Director and Global Head of Regulatory Affairs

DCVMN-AGM
20th October 2022
The 100-day mission requires a paradigm shift

Vaccine development timeline

Year

<table>
<thead>
<tr>
<th>Year</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Traditional +5 years</td>
<td>Research</td>
<td>Phase I</td>
<td>Phase II</td>
<td>Phase III</td>
<td>Filing &amp; Review</td>
<td>Manufacturing</td>
</tr>
<tr>
<td>COVID-19</td>
<td>350 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compressed timelines</td>
<td>250-300 days</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Paradigm shift

100 days

Readiness
Pre-outbreak

Response
Between outbreak & initial vaccine availability for use

Roll-out and review
Post initial availability for use

Publ. 02Mar'22 at NEJM.org
DOI: 10.1056/NEJMp2202669
Prepare, Develop, Deploy are essential for future outbreaks

Partnering with regulatory authorities worldwide and other key stakeholders to capitalise on lessons learnt and embed regulatory innovation

Prepare

Enable maximal use of platform data and pre-approved documentation

Develop

Evaluate product development pathways for any acceleration / streamlining

Identify circumstances to accelerate development and deployment based on anticipated benefit risk

Deploy

Harmonise outbreak ready pathways and maximize speed of review and regulatory reliance to enable rapid regional and global roll-out