MVC-COV1901
Evidence of vaccine safety, developer’s perspective

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MEDIGEN VACCINE BIOLOGICS CORP
DISCLAIMER:

By their very nature, forward-looking statements for a development process involve inherent risks and uncertainties, both general and specific. Thus there is no assurance or guarantee that any predictions, forecasts, projections and other forward-looking statements will be achieved.

Given the unprecedented circumstances of the COVID-19 pandemic, regulatory uncertainty, funding and rapid production development schedule, all numbers and data presented as well as schedule must be subject to adaptations and change.
# CURRENT VACCINE PROFILE

<table>
<thead>
<tr>
<th>Attributes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technology</strong></td>
<td>CHO cell derived spike protein (Subunit)</td>
</tr>
<tr>
<td><strong>Route of administration</strong></td>
<td>Intramuscular</td>
</tr>
<tr>
<td><strong>Dosage schedule</strong></td>
<td>2 doses 4 weeks apart</td>
</tr>
<tr>
<td><strong>Target population</strong></td>
<td>adults, &gt;12 years of age, including the elderly. Upon success, further age-de-escalation to children, &amp; escalate into special risk groups such as immunocompromised subjects.</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>Liquid - Fully formulated, no mixing or dilution needed. Antigen: S-2P protein (15 mcg) Adjuvant 1: CpG 1018 (750 mcg) Adjuvant 2: Al(OH)3 (375 mcg)</td>
</tr>
<tr>
<td><strong>Volume</strong></td>
<td>0.5 mL</td>
</tr>
<tr>
<td><strong>Packaging</strong></td>
<td>Pre-filled Syringe &amp; Multi-dose Vials</td>
</tr>
<tr>
<td><strong>Storage</strong></td>
<td>Cold Chain, 2-8°C (9 months and ongoing)</td>
</tr>
</tbody>
</table>

Image Source: Wikipedia, the free encyclopedia
As of 30th Sep 2021, the estimated cumulative number of clinical trial subjects was 4970; the cumulative number of distribution since the International Birth Date (IBD) to 30-Sep-2021 was 942,845 doses of MVC-COVID-19 Vaccine in total. There were no new safety signals identified during the current reporting period.

Definitions:
Very common (≥1/10)
Common (≥1/100 to <1/10)
Uncommon (≥1/1000 to <1/100)
Rare (≥1/10,000 to <1/1,000)
Very Rare (< 1/10,000)
Currently unknown (Cannot be estimated based on existing data)
Established by the Taiwan CDC

A self-reporting system for monitoring post-vaccination adverse events of approved COVID-19 vaccines in Taiwan.

Tracking actively:

- The **first 30,000** registered people from each brand of vaccine with the consent of the participating individual. Each participant will be reminded regularly to report health status after vaccination.
- Individuals can still enroll if the number of registered people is more than 30,000 per brand.

Source: https://www.cdc.gov.tw/Category/MPage/uc02Kh3_q28jena2Z3AoA
COMMON SYMPTOMS WITHIN 7 DAYS AFTER FIRST DOSE OF MVC VACCINE

- Pain at the injection site
- Fatigue
- Myalgia
- Drowsiness
- Swelling at the injection site
- Headache
- Higher body temperature
- Diarrhea
- Induration at the injection site
- Insomnia
- Redness at the injection site
- Joint pain
- Wheezing or difficulty breathing
- Abdominal pain

Percentage of reported symptoms

Ratio of top 10 reported symptoms per day (MVC first dose)
EVIDENCE OF VACCINE SAFETY, DEVELOPER’S PERSPECTIVE

COMMON SYMPTOMS WITHIN 7 DAYS AFTER FIRST DOSE OF MVC VACCINE (BY AGE)

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Age Groups</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Discomfort</td>
<td>18-49</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>50-64</td>
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<td></td>
<td>65+</td>
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<td></td>
<td>18-49</td>
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<tr>
<td></td>
<td>50-64</td>
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<tr>
<td></td>
<td>65+</td>
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<tr>
<td>Pain at injection site</td>
<td>18-49</td>
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<td></td>
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<tr>
<td></td>
<td>50-64</td>
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<td>65+</td>
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<td></td>
<td>18-49</td>
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<td>65+</td>
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<tr>
<td>Fatigue</td>
<td>18-49</td>
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<td>65+</td>
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Source: https://www.cdc.gov.tw/Category/MPage/uc02Kh3_q28Jena2Z3AoA
COMMON SYMPTOMS WITHIN 7 DAYS AFTER FIRST DOSE OF MVC VACCINE (BY AGE)

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<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 7</th>
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</thead>
<tbody>
<tr>
<td>Myalgia</td>
<td>18-49</td>
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<td></td>
<td>50-64</td>
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<td>65+</td>
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<td></td>
<td>65+</td>
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<tr>
<td>Headache</td>
<td>18-49</td>
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<td></td>
<td>50-64</td>
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<td>65+</td>
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<td></td>
<td>65+</td>
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<tr>
<td>Chills</td>
<td>18-49</td>
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<td></td>
<td>50-64</td>
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Aug 30, 2021 Source: https://www.cdc.gov.tw/Category/MPage/ucr02Kh3_q28Iena2Z3AaOa
COMMON SYMPTOMS WITHIN 7 DAYS AFTER FIRST DOSE OF MVC VACCINE (BY AGE)

- **Fever**
  - Day 1: 18-49, 50-64, 65+, 80+
  - Day 2: 18-49, 50-64, 65+, 80+
  - Day 3: 18-49, 50-64, 65+, 80+
  - Day 7: 18-49, 50-64, 65+, 80+

- **Swelling**
  - Day 1: 18-49, 50-64, 65+, 80+
  - Day 2: 18-49, 50-64, 65+, 80+
  - Day 3: 18-49, 50-64, 65+, 80+
  - Day 7: 18-49, 50-64, 65+, 80+

- **Drowsiness**
  - Day 1: 18-49, 50-64, 65+, 80+
  - Day 2: 18-49, 50-64, 65+, 80+
  - Day 3: 18-49, 50-64, 65+, 80+
  - Day 7: 18-49, 50-64, 65+, 80+

**AGE:**
- 18-49
- 50-64
- 65+
- 80+

Aug 30, 2021 Source: [https://www.cdc.gov.tw/Category/MPage/uc02Kh3_q28Jena2Z3AoA](https://www.cdc.gov.tw/Category/MPage/uc02Kh3_q28Jena2Z3AoA)
EVIDENCE OF VACCINE SAFETY, DEVELOPER’S PERSPECTIVE

COMMON SYMPTOMS WITHIN 7 DAYS AFTER FIRST DOSE OF MVC VACCINE (BY AGE)

Percentage

Day 1 Day 2 Day 3 Day 4 Day 5 Day 6 Day 7

Incapable to work Impact on daily activity Seek medical attention

Aug 30, 2021 Source: https://www.cdc.gov.tw/Category/MPage/uc02Kh3_o28Jena2Z3AoA
Safety and immunogenicity of CpG 1018 and aluminium hydroxide-adjuvanted SARS-CoV-2 S-2P protein vaccine MVC-COV1901: interim results of a large-scale, double-blind, randomised, placebo-controlled phase 2 trial in Taiwan

Szu-Min Hsieh, MD » Ming-Che Liu, MD » Prof Yen-Hsu Chen, MD » Wen-Sen Lee, MD » Prof Shinn-Jang Hwang, MD » Shu-Hsing Cheng, MD » et al.  Show all authors  Show footnotes

Published: October 13, 2021  DOI: https://doi.org/10.1016/S2213-2600(21)00402-1  Check for updates
EVIDENCE OF VACCINE SAFETY, DEVELOPER’S PERSPECTIVE

SOLICITED LOCAL ADVERSE EVENTS OCCURRING WITHIN 7 DAYS AFTER FIRST & SECOND DOSES OF MVC-COV1901

Source: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00402-1/fulltext
SOLICITED SYSTEMIC ADVERSE EVENTS OCCURRING WITHIN 7 DAYS AFTER FIRST & SECOND DOSES OF MVC-COV1901

Source: https://www.thelancet.com/journals/lanres/article/PiIS2213-2600(21)00402-1/fulltext
1. COVID-19 vaccine adverse event notification abstract

2. COVID-19 vaccine statistics
https://www.cdc.gov.tw/Category/Page/9jFXNbCe-sFK9ElmRRi2Og

3. Notification of adverse events after COVID-19 vaccination
https://www.cdc.gov.tw/Category/MPage/Q8n9n-Q4aBpRrGnKVGfkng

4. Taiwan V-Watch COVID-19 vaccine inoculation - health reporting
https://www.cdc.gov.tw/Category/MPage/ucz02Khr3_q28Jena2Z3AoA
• Most common reported events within 7 days after the first dose of Medigen vaccine:
  ➢ Systemic: fatigue, myalgia and headache
  ➢ Local: pain and swelling at injection site

• Individuals aged between 18 to 49 reported events more frequently than those between 50 to 64 or above 65.

• Safety data of 6 months post-vaccination (Phase II, N>3,000) by Nov 2021.

• As of 22 Oct, 1,362,524 doses administered. Ongoing efforts to capture safety signals to inform large scale pharmacovigilance studies.