

# Janssen COVID-19 Vaccine

Janssen Pharmaceutical Companies of Johnson & Johnson

Advisory Committee on Immunization Practices

April 23, 2021

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**Janssen**

## Important and Unique Benefits of Janssen COVID-19 Vaccine Outweigh Risks in Global Effort to Fight COVID-19

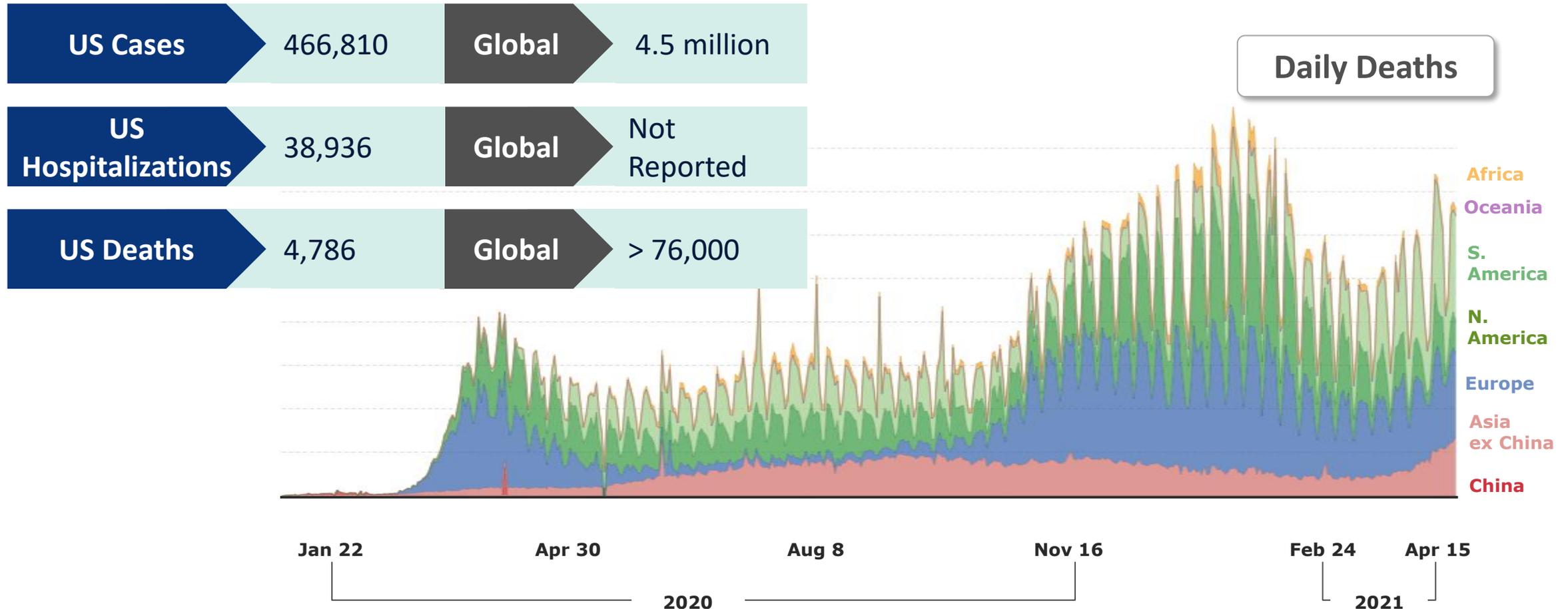
- 7.9 million in United States have received Janssen COVID-19 vaccine
- Vital and important option for many; Uniquely good option for some
  - Particular benefits for those who face barriers to healthcare services
  - Highly protective efficacy against global variants of concern
- Together with health authorities and using various surveillance systems, identified very rare side effect: thrombosis with thrombocytopenia
  - Increased awareness among general public and healthcare professionals
  - Goal: more identifiable, diagnosable, and treatable

# Agenda

- Dynamic landscape of COVID-19 pandemic: emerging variants
- Janssen COVID-19 vaccine
  - Efficacy
  - Key attributes
  - Characterization of thrombosis with thrombocytopenia
- Balancing benefit and risk

# The Global Pandemic Continues: Dynamic Landscape of COVID-19

7-Day moving average



Data: Source: CDC COVID Tracker

Image: adapted from Johns Hopkins University CSSE COVID-19 Data.

# Strong Vaccine Efficacy, Important Option As Variants Emerge in US



## Pivotal Study 3001 (N=44,325)

### 85% vaccine efficacy against severe COVID-19 > Day 28 in the United States

- Protection starts by Day 7, indicating early onset of protection
- 100% protection against COVID-19 related hospitalizations (> Day 28) and deaths
- Consistent vaccine efficacy against severe disease across all regions

### Highly protective against global variants of concern

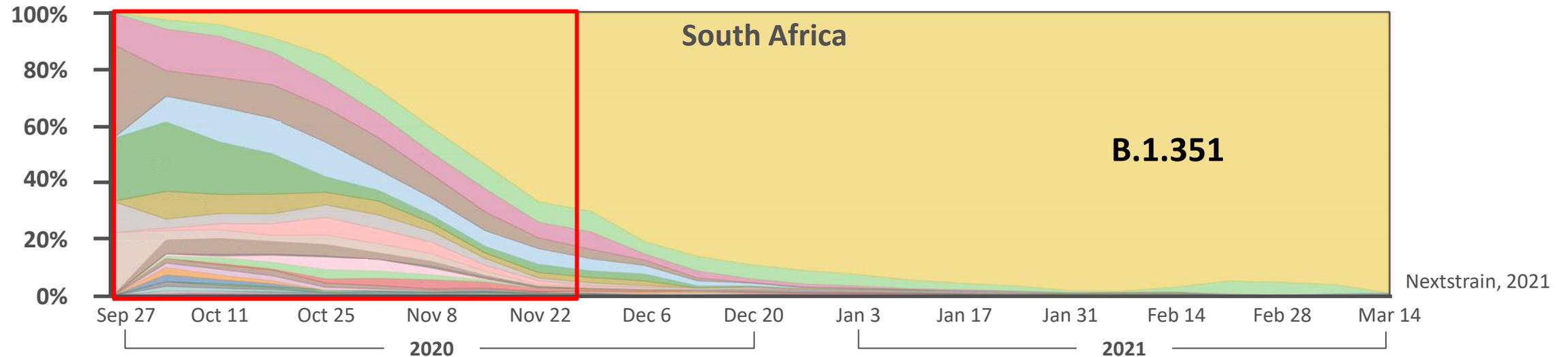
- Equally high protection in South Africa (n > 6,500) where B.1.351 (> 95%) is highly prevalent and in Brazil (n > 4,912) where P.2 lineage (69%) is highly prevalent



## Ongoing South Africa study supports strong effectiveness in presence of B.1.351

- Open-label healthcare worker study (N=288,368 vaccinated)
  - Primarily women (76%), mostly people under 50 years old (75%)
- 4 COVID-19-related deaths (0.001%) (D4, 7, 7, 20) and no deaths post-day 28
- Of 17 (0.006%) COVID-19 breakthrough cases, 3 occurred after Day 28 (D31, 31, 34)

## B.1.351, Which Includes 484 Mutation, Became Dominant Variant in South Africa in Matter of Weeks



- B.1.351 became nearly only variant circulating in South Africa 8 weeks after first appearance
- Now found in 36 of 50 US states / territories and across Europe
- As with B.1.351, other variants containing the key mutation of position E484K emerging in US

# Single-Dose Vaccine Plays Essential, Unique Role in Urgent Effort to Contain Virus

## 1-Dose Vaccine

- Only authorized COVID-19 vaccine single-dose regimen
- Critical option for rural and transient populations

## Early Onset, Durable Response

- Vaccine efficacy against severe disease seen by Day 7 in pivotal trial
- Durable immune response based on platform, early COVID-19 data

## Simple Shipping, Storage

- Compatible with all existing distribution channels
- Stored at normal refrigerator temperatures
- Can reach remote locations

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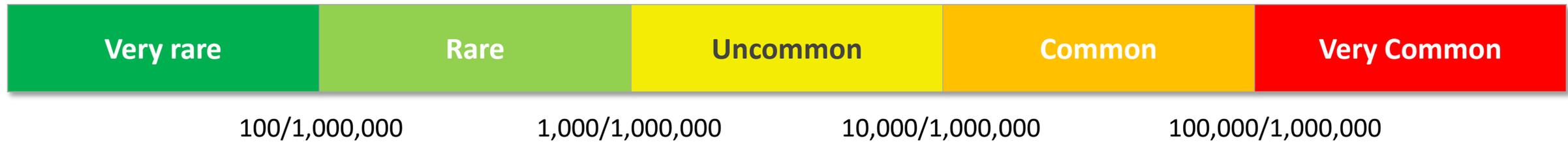
April 23, 2021

**Joanne Waldstreicher, MD**

**Chief Medical Officer**

**Johnson & Johnson**

# Thrombosis with Thrombocytopenia: Post-Authorization Cases Reported after Janssen Vaccine



## Reported Thrombosis with Thrombocytopenia

15 cases/7.98M people  
vaccinated<sup>1</sup>

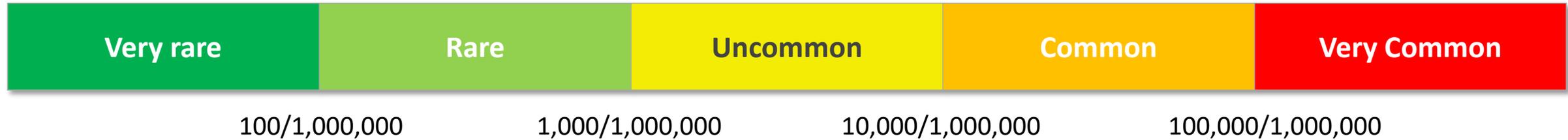
**1.9 cases/million people**

1. Cases, # people vaccinated: CDC (April 22)

# Thrombosis with Thrombocytopenia: Post-Authorization Cases Reported after Janssen Vaccine and Background

Background CVST with  
Thrombocytopenia  
**0.1/million people<sup>2</sup>**

Incidence proportion (cases/million people)



Reported Thrombosis with  
Thrombocytopenia

15 cases/7.98M people  
vaccinated<sup>1</sup>

**1.9 cases/million people**

1. Cases, # people vaccinated: CDC (April 22)
2. Incidence based on CVST + Thrombocytopenia in 2018 from 5 observational sources (n=63 million persons)

# Thrombosis with Thrombocytopenia: Post-Authorization Cases Reported after Janssen Vaccine and Other Adverse Events

Intussusception in rotavirus  
vaccine  
16-69<sup>5-6</sup>

Immune thrombocytopenia  
in MMR vaccine  
26<sup>4</sup>

GBS in H1N1 influenza vaccine  
3.4<sup>3</sup>

Anaphylaxis in any non-COVID  
vaccine  
1.2<sup>2</sup>

Heparin-induced thrombocytopenia  
1,000 - 50,000<sup>7</sup>

Incidence proportion (cases/million people)



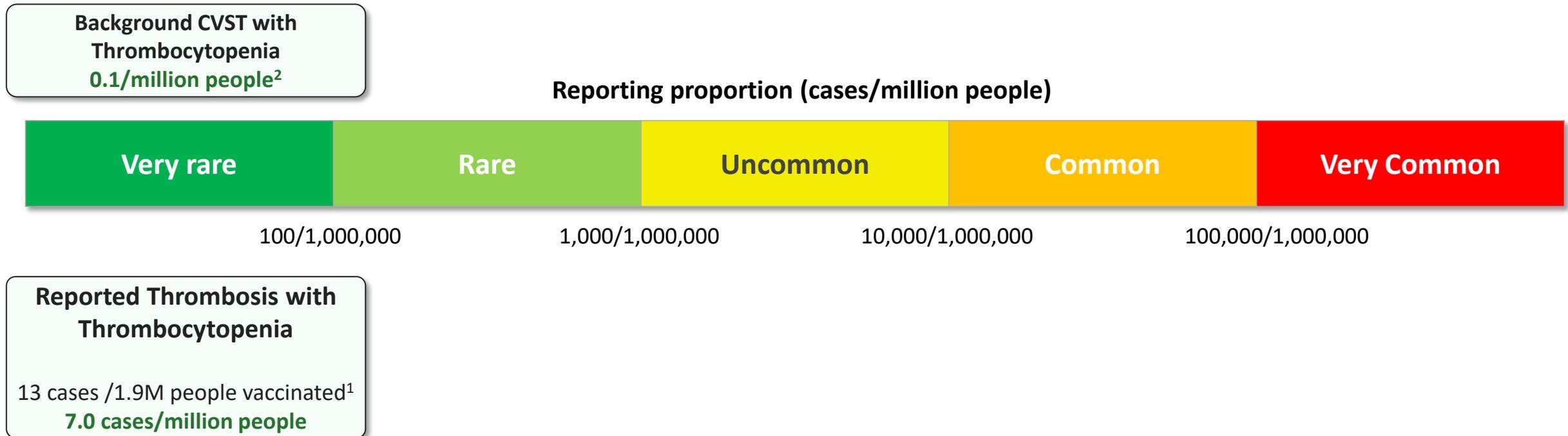
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1. Cases, # people vaccinated: CDC (April 22)
2. McNeil, M. et al. JACI. 2016. <http://dx.doi.org/137.3.2015.10.1016/j.jaci.2015.07.048>
3. Salmon. et al. Lancet. 2013 (IR = IRR\*baseline risk = 2.5\*1.2/100,000py)
4. Mantadakis, E. J Pediatr. 2010. DOI: 10.1016/j.jpeds.2009.10.015. Epub. PMID: 20097358
5. Rha, B. et al. 2014. DOI: 10.1586/14760584.2014.942223
6. Jiang, J. et al. 2013. <https://doi.org/10.1371/journal.pone.0068482>
7. Hogan, M. et al. Vasc Med. 2020. DOI: 10.1177/1358863X19898253. Epub. PMID: 32195628.

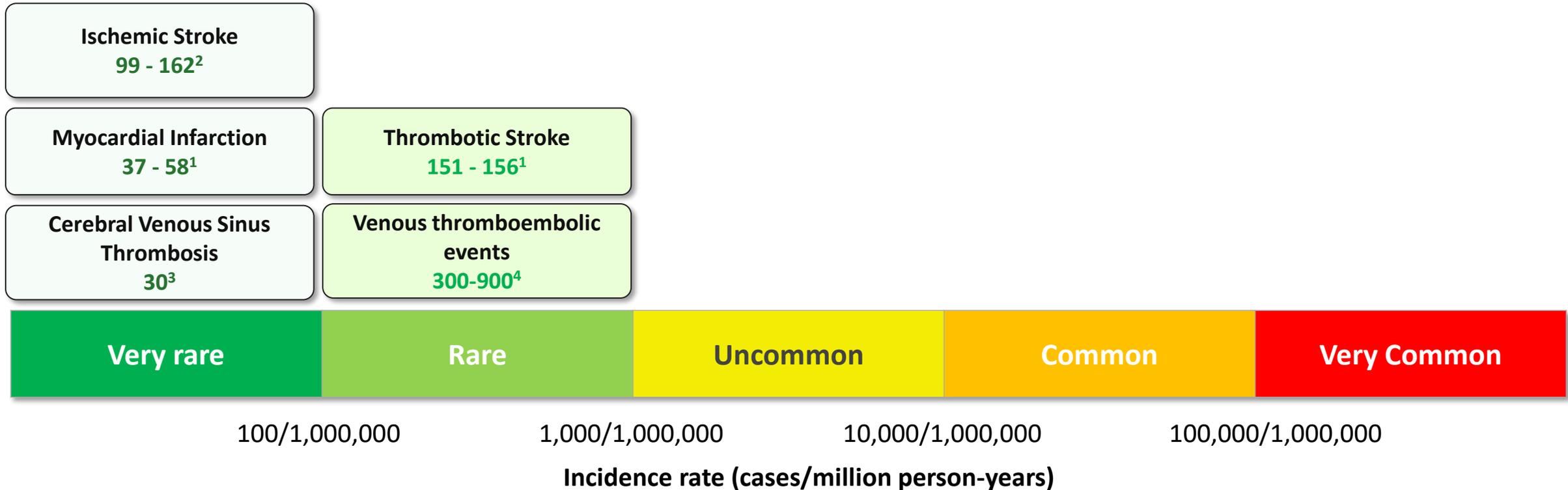
# Thrombosis with Thrombocytopenia: Post-Authorization Cases Reported after Janssen Vaccine in Women Age < 50 and Background



1. Cases, # people vaccinated: CDC (April 22)

2. Background rate in 1JAN2018 from 5 US observational sources (n=63 million persons), \* 28/365d (time-at-risk)

# Known and Labeled Risks For Combination Oral Contraceptives in Women

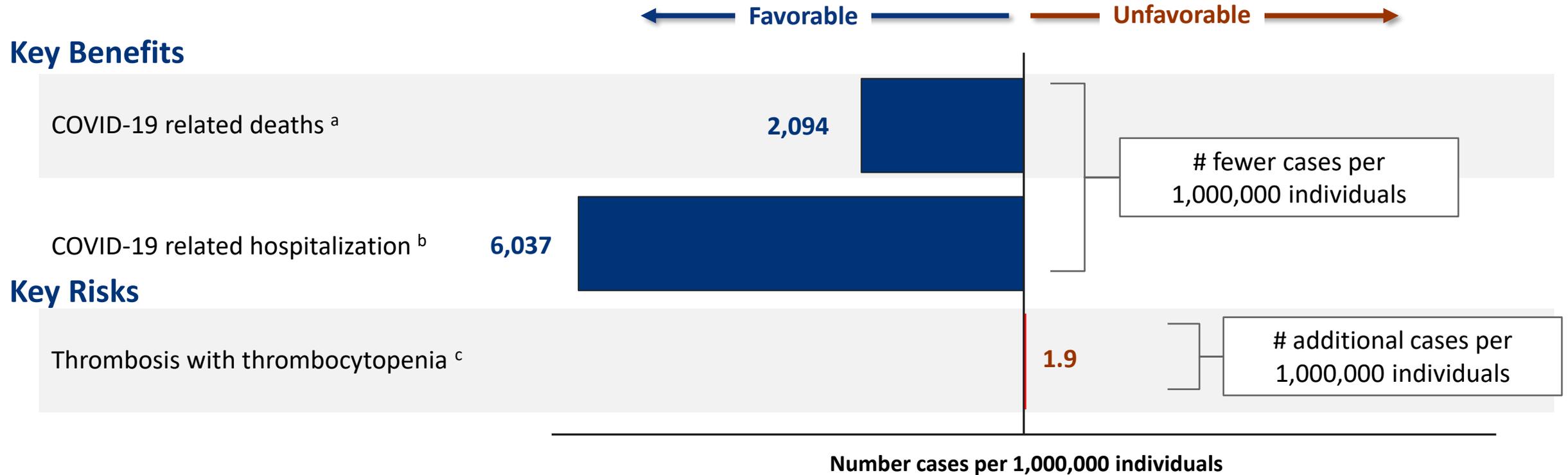


All data from published literature (other than venous thromboembolic events: source is product label)

1. Lidegaard, O. et al. NEJM. 2012
2. Weill, A. et al. BMJ. 2016
3. Azomegar. et al. Frontiers in Neurology. 2015 (IR=background rate \* OR = 0.4/100,000 \* 7.59)
4. Yasmin package insert: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=d7ea6a60-5a56-4f81-b206-9b27b7e58875>

# Favorable Benefit-Risk Assessment in Adults 18 Years and Older

Vaccinating 1M adults 18 years and older in the US would be expected to result in:



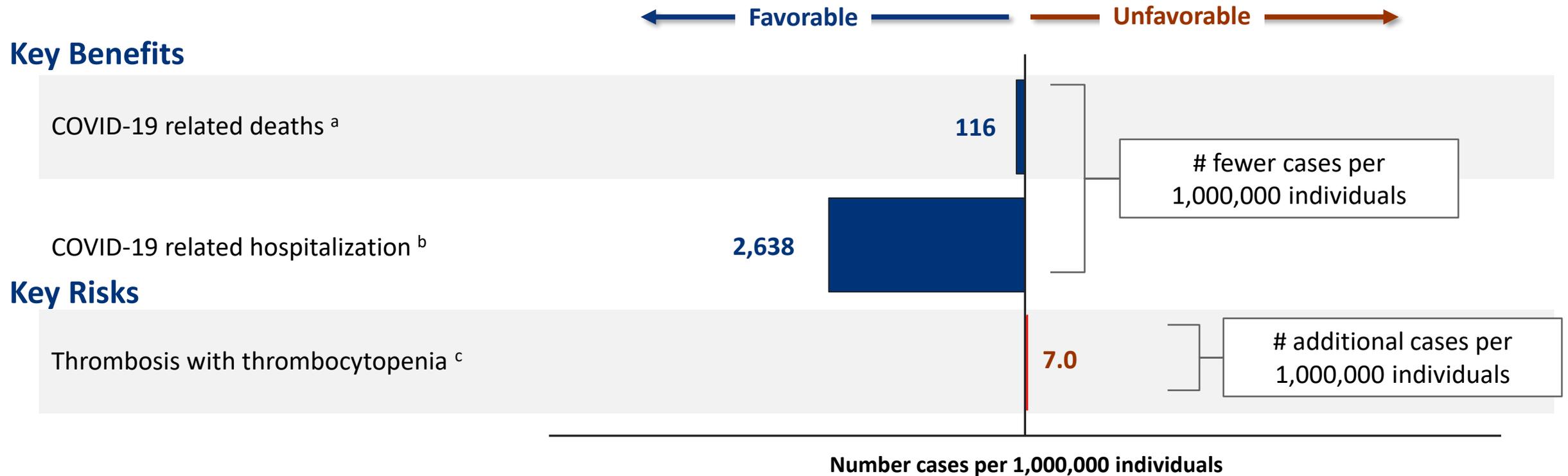
a. CDC COVID-19 mortality rate as of Apr 14, 2021, 2018 US census population, COV3001 interim analysis assuming 100% efficacy on death for 1-year post-vaccination

b. CDC COVID-19 hospitalization rate from Mar 7, 2020 – Mar 6, 2021, COV3001 interim analysis assuming 100% efficacy on hospitalization for 1-year post-vaccination

c. Observed: Reporting proportion; Background: Assumed 0 cases/million

# Favorable Benefit-Risk Assessment in Women Age < 50

Vaccinating 1M women age < 50 in the US would be expected to result in:



a. CDC COVID-19 mortality rate as of Apr 14, 2021, 2018 US census population, COV3001 interim analysis assuming 100% efficacy on death for 1-year post-vaccination

b. CDC COVID-19 hospitalization rate from Mar 7, 2020 – Mar 6, 2021, COV3001 interim analysis assuming 100% efficacy on hospitalization for 1-year post-vaccination

c. Observed: Reporting proportion; Background: Assumed 0 cases/million

# Janssen Supports Public Awareness, and Guidance for Medical Professionals of this Very Rare Event Following Vaccination

- Active follow up to identify and investigate cases, understand underlying pathophysiology
- Designed observational study protocols using multiple databases
- Support guidance from CDC and professional societies that outline education, diagnosis and treatment
- Implementing HCP and consumer support initiatives; professional initiatives
  - Vaccine fact sheets on Janssen healthcare and consumer websites
  - 24-hour global hotline
- Agree with FDA on warning in label and alerting vaccinees with communications materials

# FDA-agreed Warning and Precaution Regarding Thrombosis with Thrombocytopenia

## 5.2 Thrombosis with Thrombocytopenia

Reports of adverse events following use of the Janssen COVID-19 Vaccine under emergency use authorization suggest an increased risk of thrombosis involving the cerebral venous sinuses and other sites (including but not limited to the large blood vessels of the abdomen and the veins of the lower extremities) combined with thrombocytopenia and with onset of symptoms approximately one to two weeks after vaccination [see *Overall Safety Summary (6.2)*]. Most cases of thrombosis with thrombocytopenia reported following the Janssen COVID-19 Vaccine have occurred in females ages 18 through 49 years; some have been fatal. Specific risk factors for thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine and the level of potential excess risk due to vaccination are under investigation. Based on currently available evidence, a causal relationship between thrombosis with thrombocytopenia and the Janssen COVID-19 Vaccine is plausible.

# FDA-agreed Warning and Precaution Regarding Thrombosis with Thrombocytopenia

## 5.2 Continued

Healthcare professionals should be alert to the signs and symptoms of thrombosis with thrombocytopenia in individuals who receive the Janssen COVID-19 Vaccine. The clinical course shares features with autoimmune heparin-induced thrombocytopenia. In individuals with suspected thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine, the use of heparin may be harmful and alternative treatments may be needed. Consultation with hematology specialists is strongly recommended. The American Society of Hematology has published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine (<https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>).

Recipients of Janssen COVID-19 Vaccine should be instructed to seek immediate medical attention if they develop shortness of breath, chest pain, leg swelling, persistent abdominal pain, neurological symptoms (including severe or persistent headaches or blurred vision), or petechiae beyond the site of vaccination.

# Benefits of an Effective, Single-Dose, Easy-to-Use Janssen COVID-19 Vaccine Continue to Outweigh Risks

- Continue to face deadly pandemic, variants making containment more challenging globally
  - Janssen COVID-19 vaccine critically important to help halt spread of infection
- Janssen vaccine offers early and durable efficacy, protection against variants, and simplicity
  - Provides access to certain populations that typically face barriers to healthcare services
- Concerns that a restriction would leave significant proportion of the US unvaccinated
  - Puts reaching herd immunity at risk
- Janssen committed to understanding and communicating all risks, including very rare events of thrombosis with thrombocytopenia
  - Supports awareness, education and labeling; making this event more identifiable, diagnosable and treatable with improved chances for successful outcomes
- Janssen COVID-19 vaccine central in effort to end pandemic

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