Centers for Disease Control and Prevention

Mpox Vaccine Work Group

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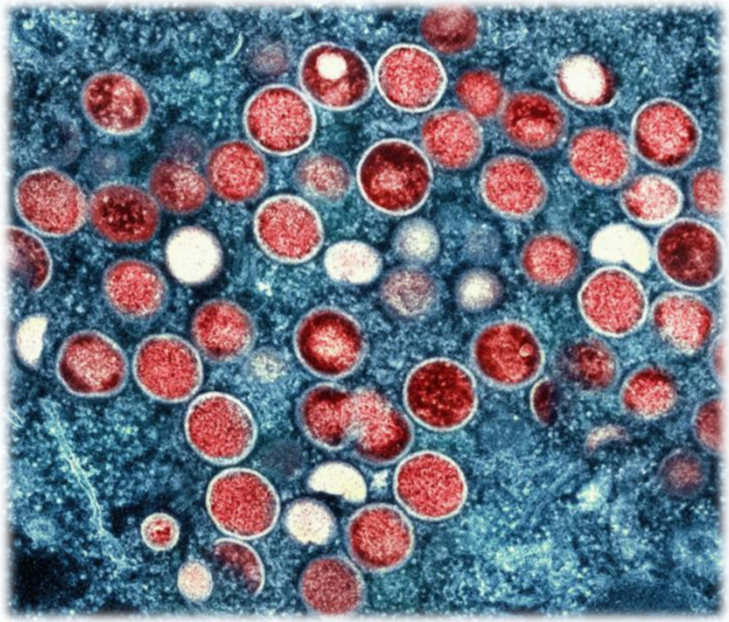
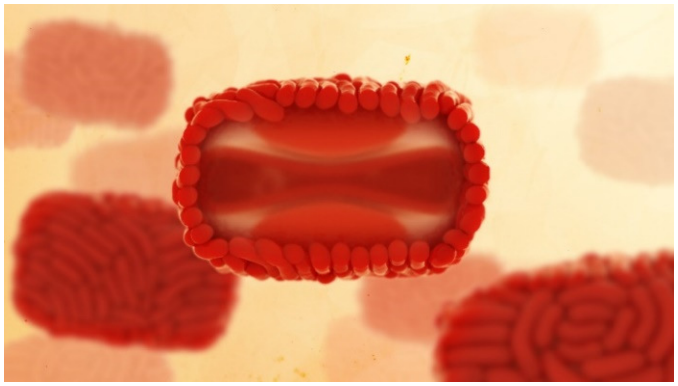
Centers for Disease Control and Prevention



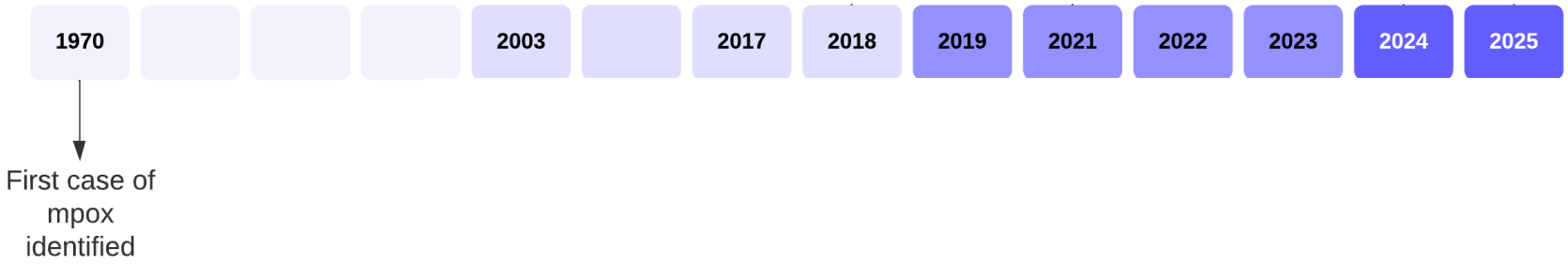
ACIP Meeting
April 15, 2025

Monkeypox virus (MPXV)

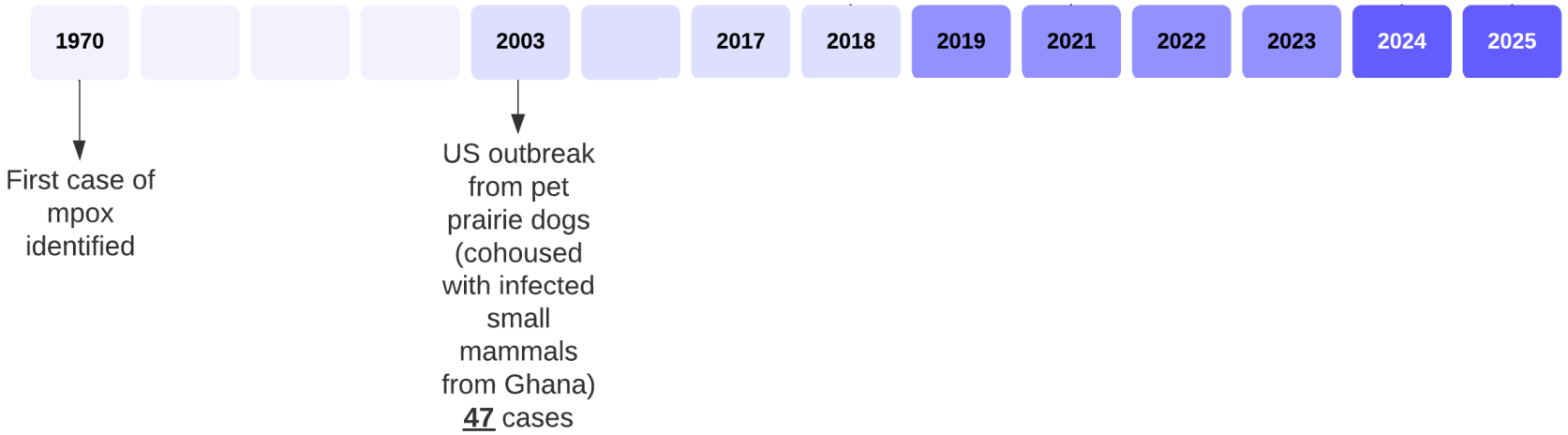
- Genus: *Orthopoxvirus*
- Family: *Poxviridae*
- Discovered in 1958 after two pox-like disease outbreaks in research monkey colonies
- Specific animal reservoir unknown, but likely African small mammals
- On November 28, 2022, WHO implemented the preferred term “mpox” for the disease
- Two clades of MPXV:
  - Clade I: found in central Africa and historically associated with greater disease severity in a higher proportion of people
  - Clade II: found in West Africa and caused the 2022 global outbreak



Mpox historical context



Mpox historical context



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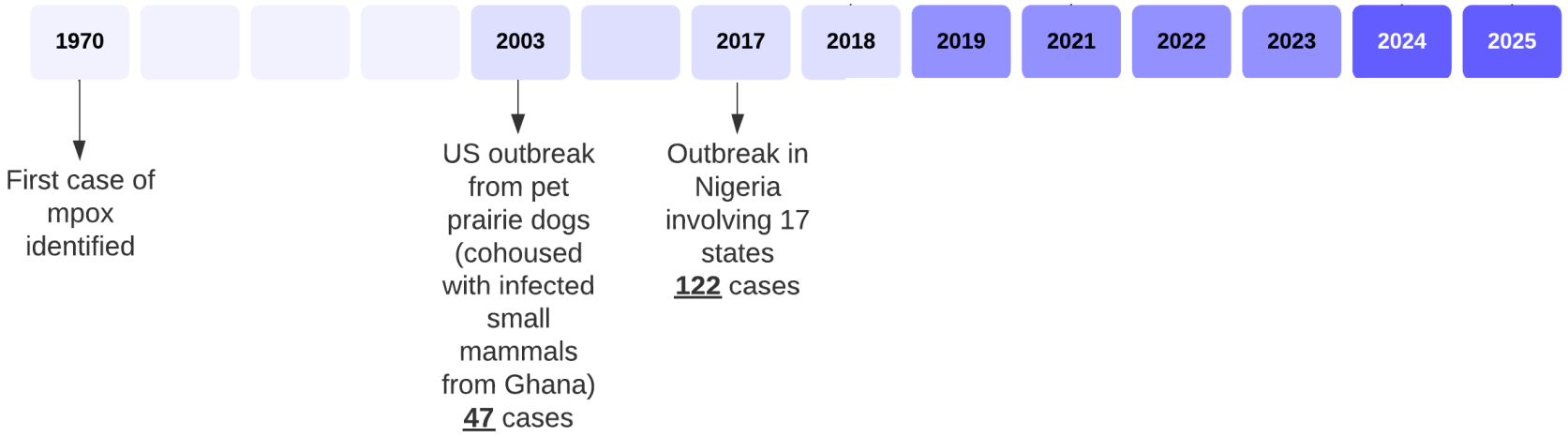

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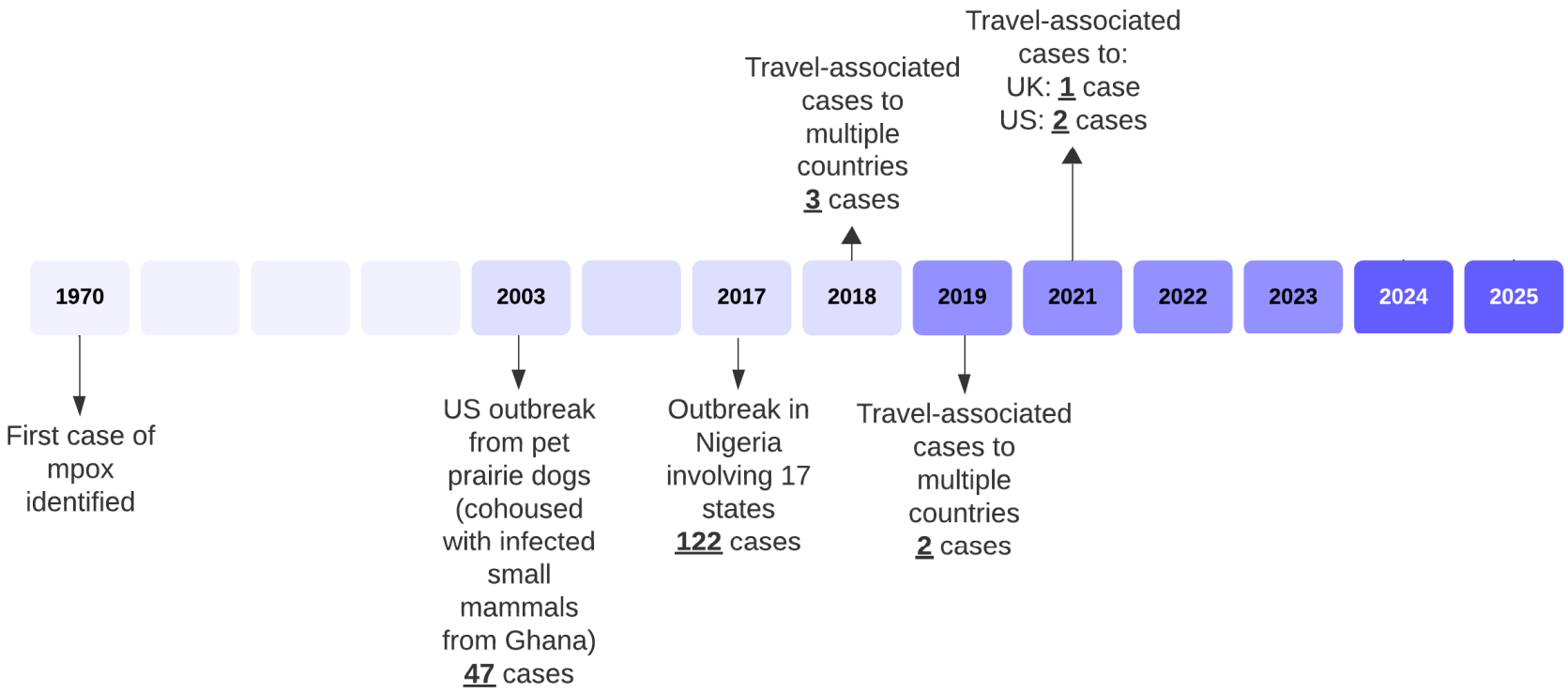

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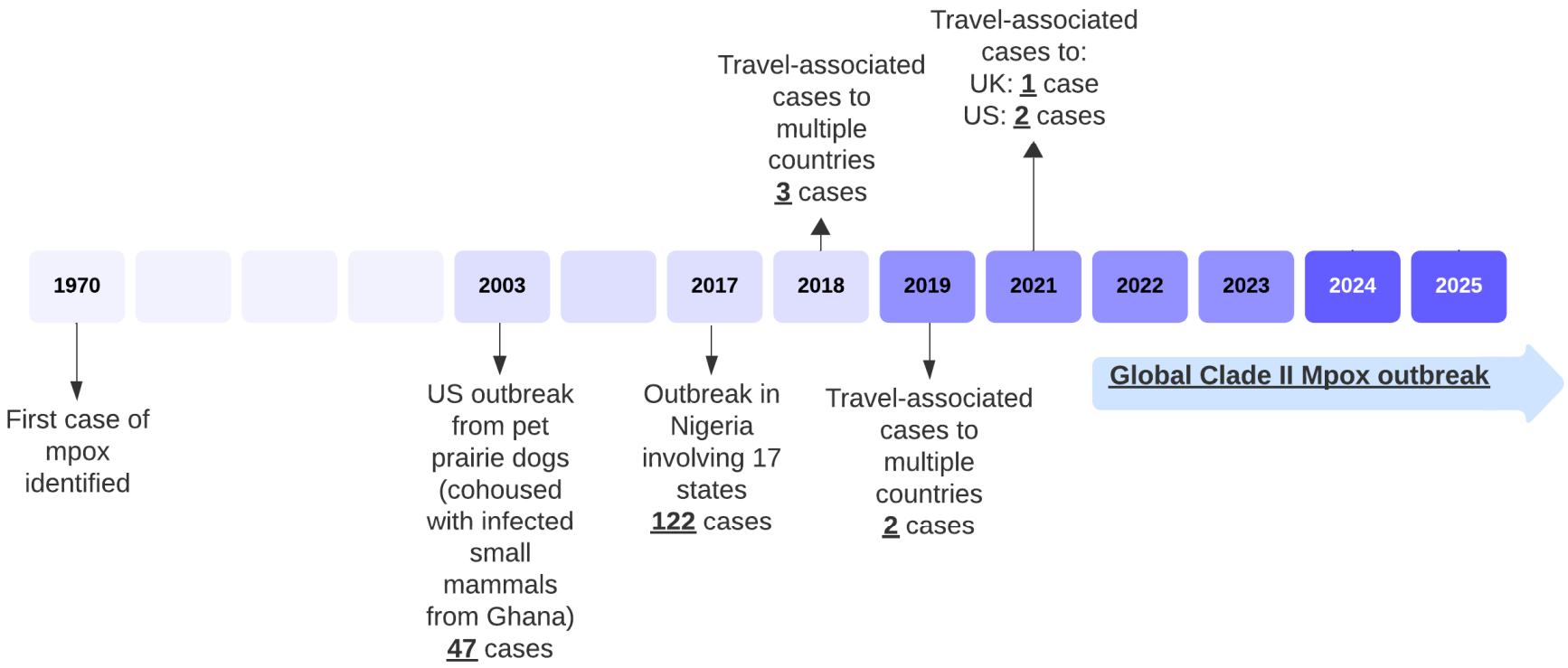
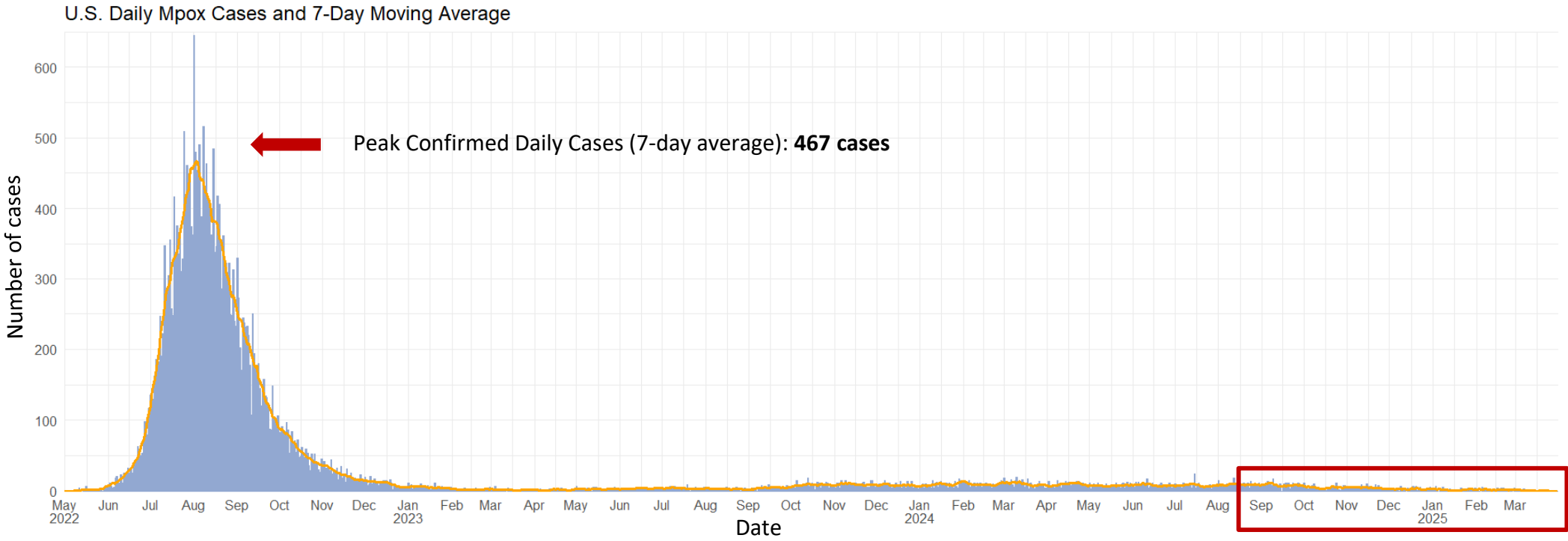


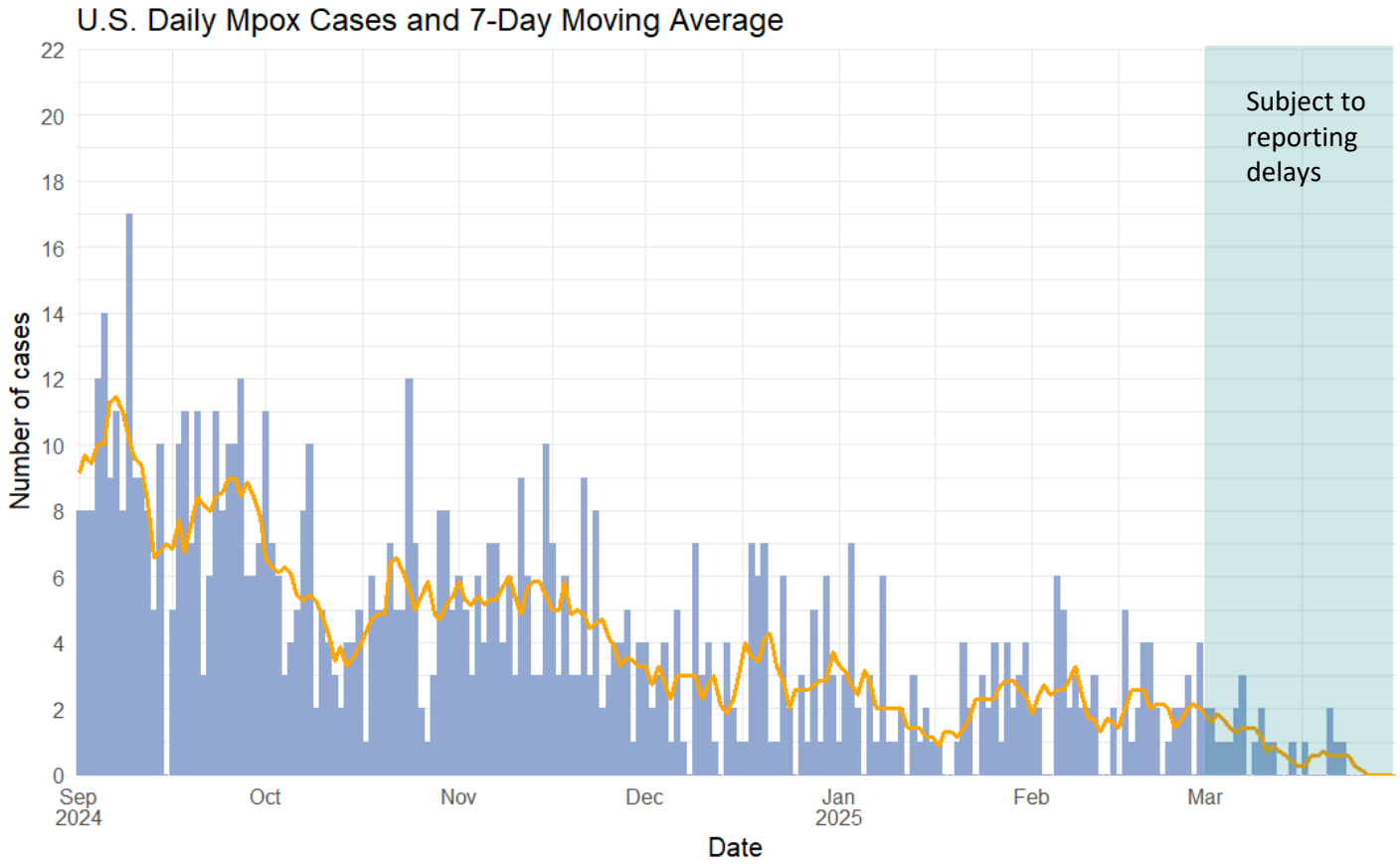
Global Mpox Outbreak, 2022

- First case in this outbreak identified in the United Kingdom in May 2022
- Primarily affecting gay, bisexual, and other men who have sex with men (MSM)
- Associated with person-to-person spread via close skin-to-skin contact including sex
- Deaths have occurred, primarily among persons with severe immunocompromise from advanced HIV
- U.S. case counts and deaths comprise 1/3 of cases and deaths globally
  - >30,000 cases
  - >60 deaths

United States mpox case count and 7-day moving Average – May 2022 through March 2025



United States mpox case count and 7-day moving Average – August 2024 through March 2025



The current median 7-day moving average for confirmed cases for February is 3.3- 1.2 per day.

Current Recommendation (voted February 2023)

- ACIP recommends the 2-dose* JYNNEOS vaccine series for persons aged 18 years and older at risk of mpox during an mpox outbreak§.

*Dose 2 administered one month after dose 1

§Public health authorities determine whether there is an mpox outbreak; a single case may be considered an mpox outbreak at the discretion of public health authorities. Other circumstances in which a public health response may be indicated include ongoing risk of introduction of mpox into a community due to disease activity in another geographic area.

Current Recommendation (voted October 2023) – updated language

ACIP recommends vaccination* with the 2-dose† JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox§?

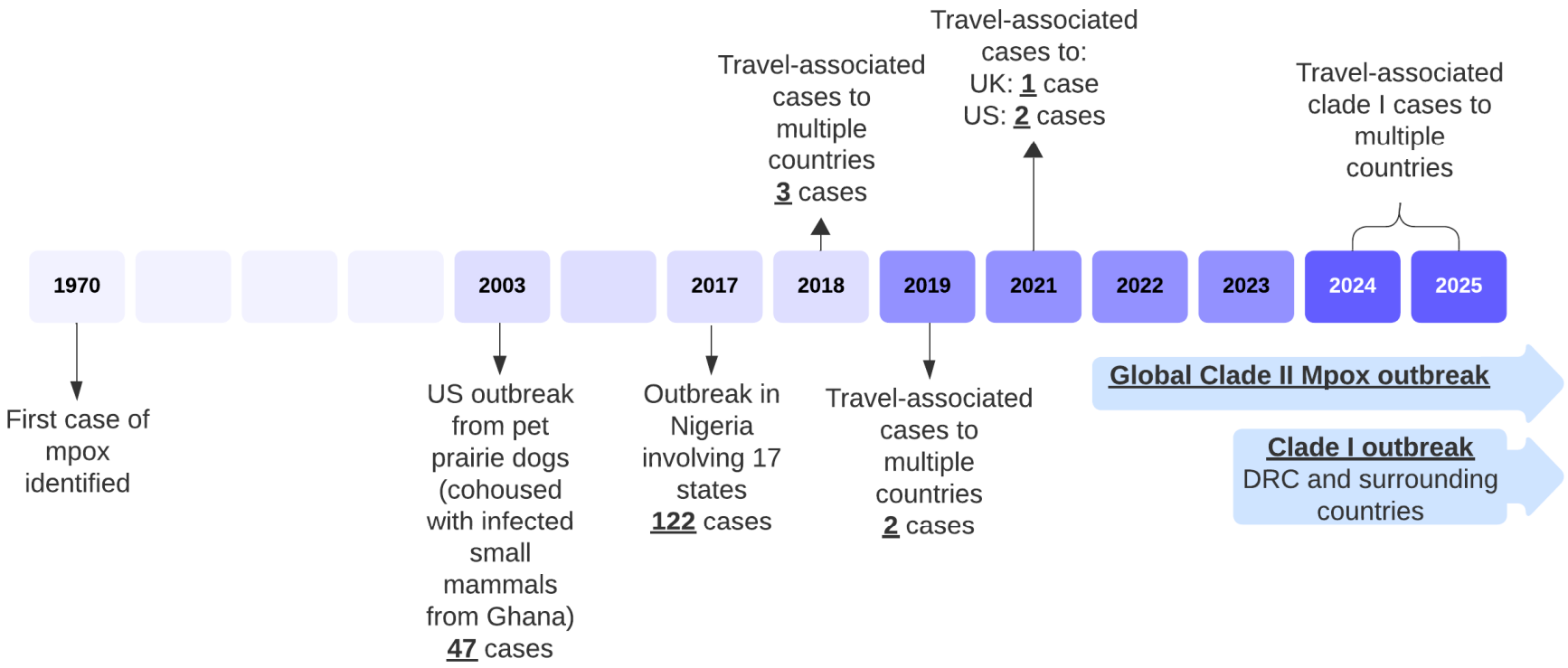
*Interim recommendation to be revisited in 2-3 years

† Dose 2 administered 28 days after dose 1

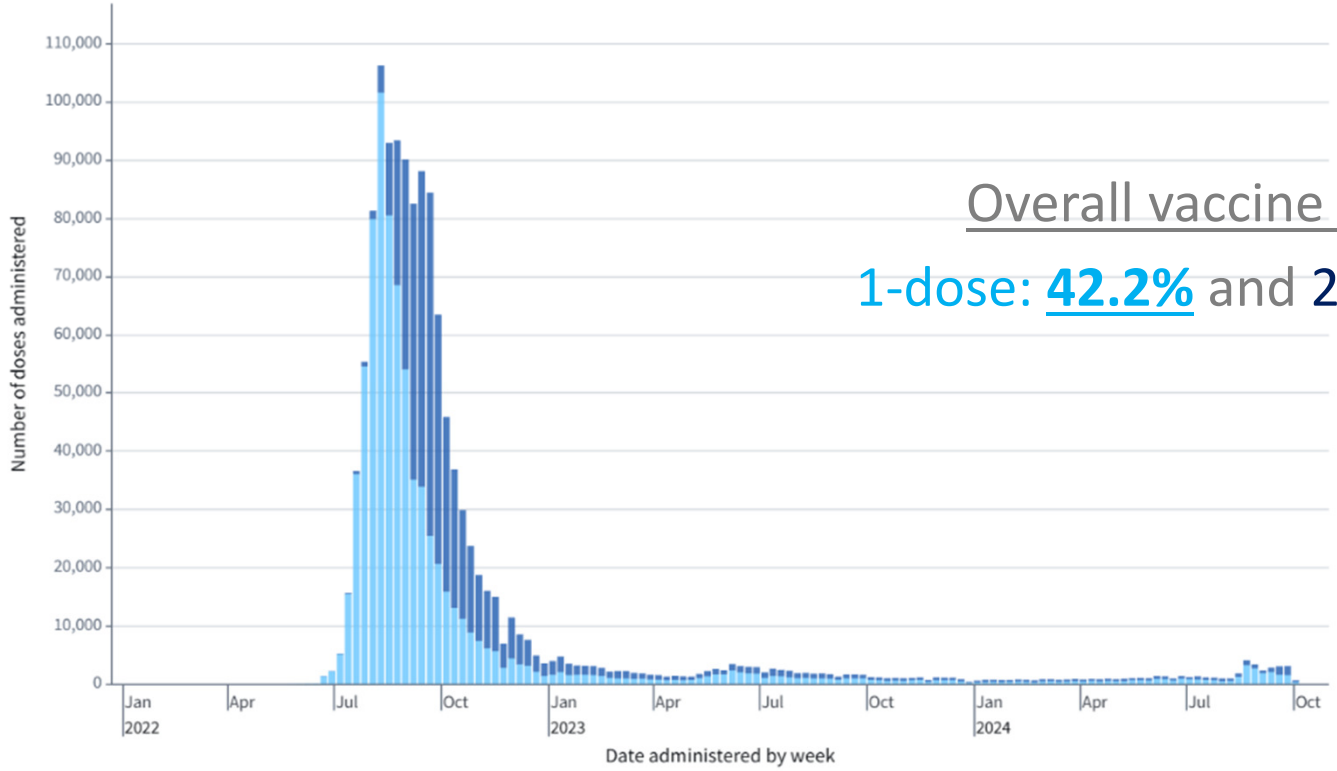
§Persons at risk:

1. Gay, bisexual, and other men who have sex with men (MSM), or a person who has sex with MSM who in the past 6 months have had one of the following:
    - A new diagnosis of ≥ 1 sexually transmitted disease
    - More than one sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
2. Sexual partners of persons with the risks described in above
3. Persons who anticipate experiencing any of the above

Mpox current situation



Jynneos vaccine coverage in the United States among people at risk for mpox – June 2022 to September 2024

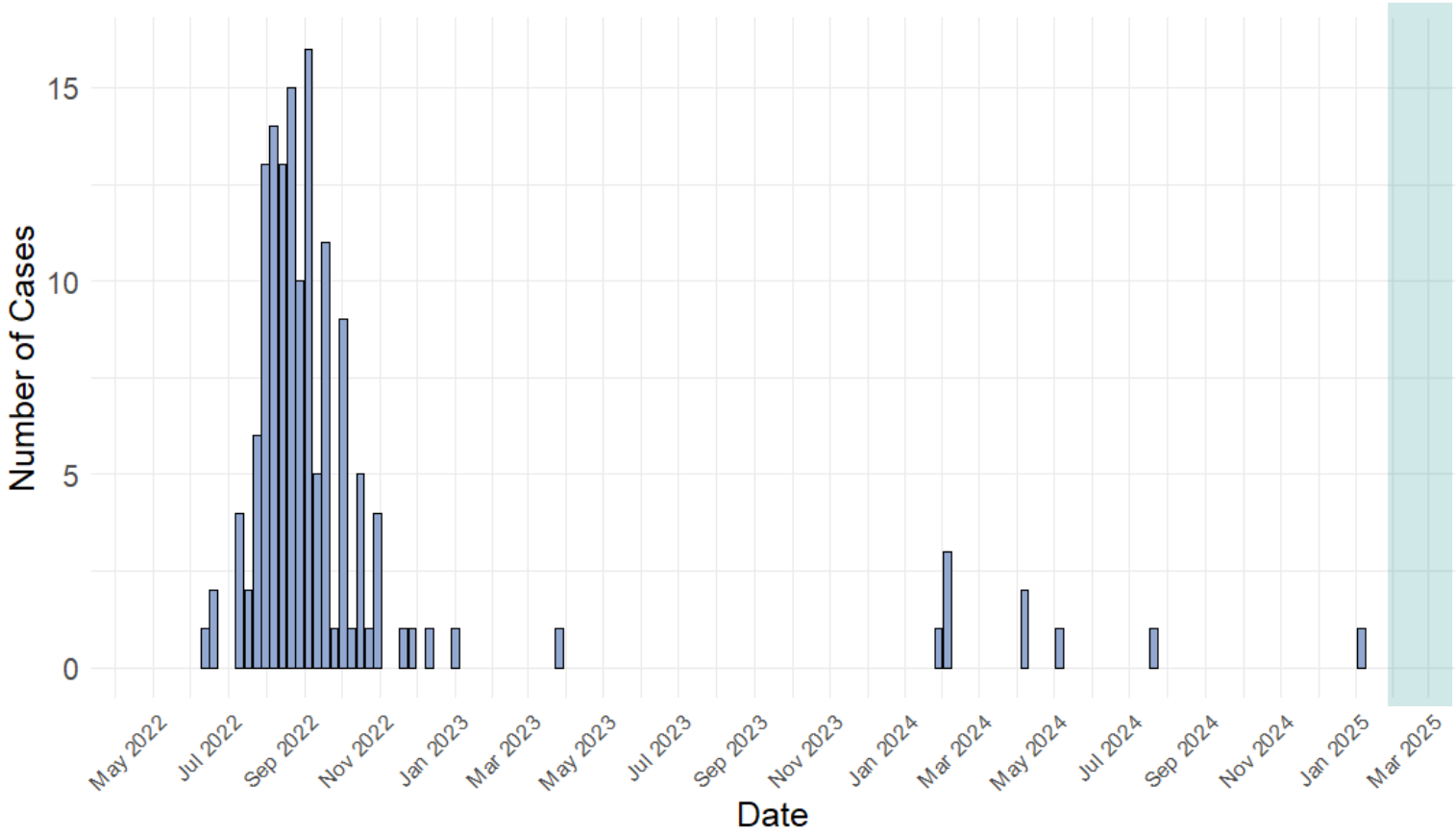


Overall vaccine coverage

1-dose: **42.2%** and 2-dose: **26.2 %**

- Modeling data suggests *any increase* in coverage reduces the risk of outbreaks, and low coverage (<50%) could promote larger outbreaks

U.S. mpox case trends in adolescents and pediatrics, May 2022 – March 2025



Subject to reporting delays

Age group	Case Count
12-17	92
6-11	17
1-5	23
<1	15
Total	**147**

New data on safety and immunogenicity in adolescents

- Previously, there was no data evaluating Jynneos in children <18 years

- An NIH sponsored trial completed last year evaluating Jynneos in 12–17-year-old adolescents
  - DMID 22-0020: A Phase 2 Randomized, Open-Label Multisite Trial to Inform Public Health Strategies Involving Use of MVA-BN Vaccine for Mpox (DoSES)
    - Stage 2: non-inferiority trial of Jynneos in adolescents compared to adults

- Proposed recommendations would *extend* current recommendations to 12–17-year-old adolescents

Proposed Recommendation 1

- ACIP recommends the 2-dose* JYNNEOS vaccine series for persons 12–17 years of age at risk of mpox during an mpox outbreak§.

*Dose 2 administered one month after dose 1
§Public health authorities determine whether there is an mpox outbreak; a single case may be considered an mpox outbreak at the discretion of public health authorities. Other circumstances in which a public health response may be indicated include ongoing risk of introduction of mpox into a community due to disease activity in another geographic area.

Proposed Recommendation 2

ACIP recommends vaccination* with the 2-dose† JYNNEOS vaccine series for persons aged 12–17 years at risk for mpox§?

*Interim recommendation to be revisited in 2-3 years

† Dose 2 administered 28 days after dose 1

§Persons at risk:

1. Gay, bisexual, and other men who have sex with men (MSM), or a person who has sex with MSM who in the past 6 months have had one of the following:
    - A new diagnosis of ≥ 1 sexually transmitted disease
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2. Sexual partners of persons with the risks described in above
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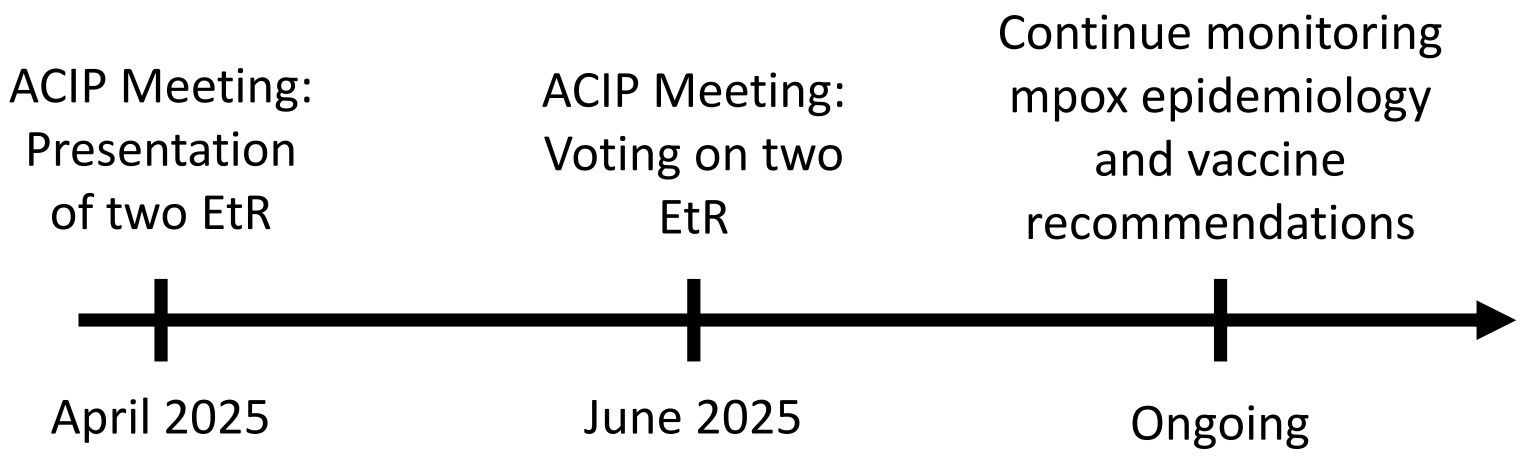
Goals for today's meeting

- Presentation of the safety and immunogenicity of Jynneos in 12–17-year-olds: Dr. C. Buddy Creech

- Evidence to recommendations framework:
  - Outbreak recommendations: Dr. Faisal Minhaj
  - Routine recommendations: Dr. Faisal Minhaj

Tentative timeline for ACIP discussions and votes



WG Composition

- **WG Chair**
  - Yvonne (Bonnie) Maldonado
- **WG Lead**
  - Faisal Syed Minhaj
- **ACIP Members**
  - Edwin Asturias
  - Lin Chen
- **Ex Officio/Liaison members**
  - CSTE: Paul Cieslak
  - ASTHO: Chris Taylor
  - NACHO: Philip Huang
  - FDA: Sixun Yang, Pete Weina
  - ACOG: Howard Minkoff
  - AAP: Jim Campbell
- **Ex Officio/Liaison members (cont.)**
  - HRSA: Vikram Krishnasamy
  - AIM: Heather Roth
  - NIH: Kimberly Taylor
  - IHS: Uzo Chukwama
  - NACI: Nicole Forbes, Joshua Montroy
  - IDSA: Shireesha Dhanireddy, Katherine Hsu
- **Invited Consultants**
  - Inger Damon
  - Stuart Isaacs
  - Mike Merchlinsky
  - Amanda Zarrabian
- **Clinician experts**

  STIs, HIV, mpox, pediatrics
  - Jason Zucker
  - Kim Workowski
  - Pablo Sánchez
  - Beth Bell

  Immunization
  - Ruth Karron
  - Flor Munoz-Rivas

CDC Contributors

- **Mpox Epi/Lab/Vaccine experts**
  - Agam Rao
  - Andrea McCollum
  - Christina Hutson
  - Sathesh Panayampalli
  - Shama Cash-Goldwasser
- **Vaccine Safety**
  - Michael McNeil
  - Jonathan Duffy
- **Regulatory Affairs**
  - Yon Yu
- **STIs and HIV**
  - Laura Bachman
  - Jesse O'Shea
- **Drug Services**
  - Julian Jolly
- **Vaccine Implementation**
  - Liz Velazquez

Thank you

For more information, contact CDC
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