

NATIONAL
ACADEMIES

Sciences
Engineering
Medicine

Review of Relevant Literature Regarding Adverse Events Associated with Vaccines

Advisory Commission on Childhood Vaccines

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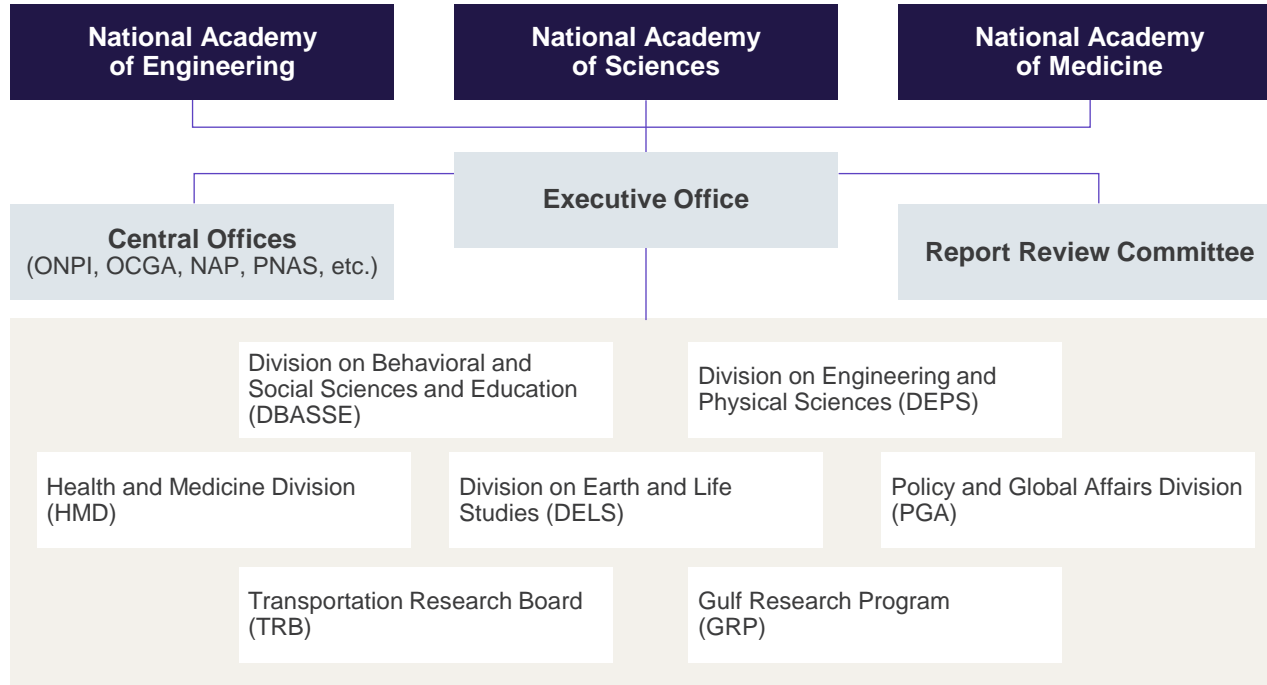


What is the National Academies of Sciences, Engineering, and Medicine?

Established by President Lincoln and Congress in 1863

- A private, not-for-profit organization that does NOT receive a line-item budget from Congress
- Comprises 3 honorific membership societies and 7 programmatic units, which provide convening functions and advisory functions
- Congress often mandates NASEM involvement in important topics, as it did in the 1986 National Childhood Vaccine Injury Act
- Under the brand of the Institute of Medicine, provided 3 comprehensive reports on the safety of vaccines for VICP (1992, 1994, 2012)
- Conducted other work on vaccines for other components of the Department of Health and Human Services

Program Units within the Academies



Key aspects of NASEM consensus committee work

Committees operate under Section 15 of the Federal Advisory Committee Act

- Subject to NASEM policies on conflict of interest and a public comment period
- Cannot meet in private with anyone from outside of NASEM
- Deliberate in closed session
- Do not share drafts other than during the confidential peer review process
- Reviewers' names disclosed in the committee report, but their comments are blinded to the committee and not made public
- Final report released to the public, NOT to the sponsor
- Reports available for free download from the National Academies Press

Statement of Task

NASEM will establish a committee of experts who will assess the biological, clinical, and epidemiological literature and include a causality assessment of:

- shoulder diagnoses to determine whether deltoid bursitis or any other specific shoulder injury may or may not be causally-related to vaccine administration, and
- specific adverse events related to COVID-19 vaccines.

The committee will issue one report in March 2024

COVID-19 vaccine-related adverse events

Guillain-Barrè Syndrome (GBS)

chronic inflammatory demyelinating
polyneuropathy (CIDP)

transverse myelitis (TM)

Bell's palsy

hearing loss

chronic headaches

infertility

sudden death

myocarditis/pericarditis

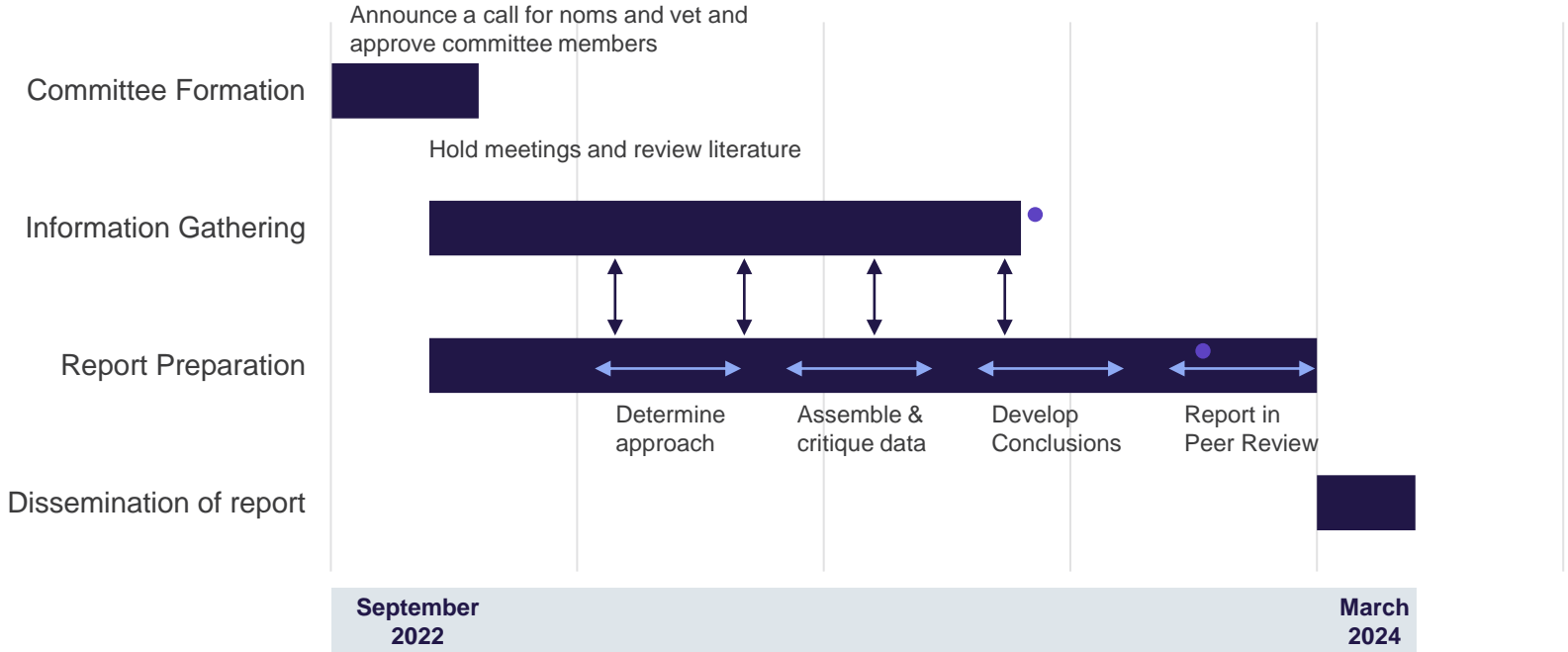
thrombosis with thrombocytopenia syndrome
(TTS)

immune thrombocytopenic purpura (ITP)

thromboembolic events (e.g., cerebrovascular
accident (CVA), myocardial infarction (MI),
pulmonary embolism, deep vein thrombosis
(DVT)

capillary leak syndrome

Typical Project Timeline



Where are we now?

- Committee approval by Dr. Marcia McNutt, NAS president, expected by next week
- Bios will be posted on our project website for a 20-day public comment period before meeting for the first time in January 2023
- In January or February 2023 committee will hear from VICP in a public session about the statement of task and discuss how past work could be more useful for all VICP stakeholders
- Committee will meet virtually and in hybrid fashion multiple times during 2023 to
 - establish methods and approach
 - review literature
 - draw conclusions
 - prepare a report
- Chair and staff available for briefings

Thank you – questions?

