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Project Orbis: results and outlook

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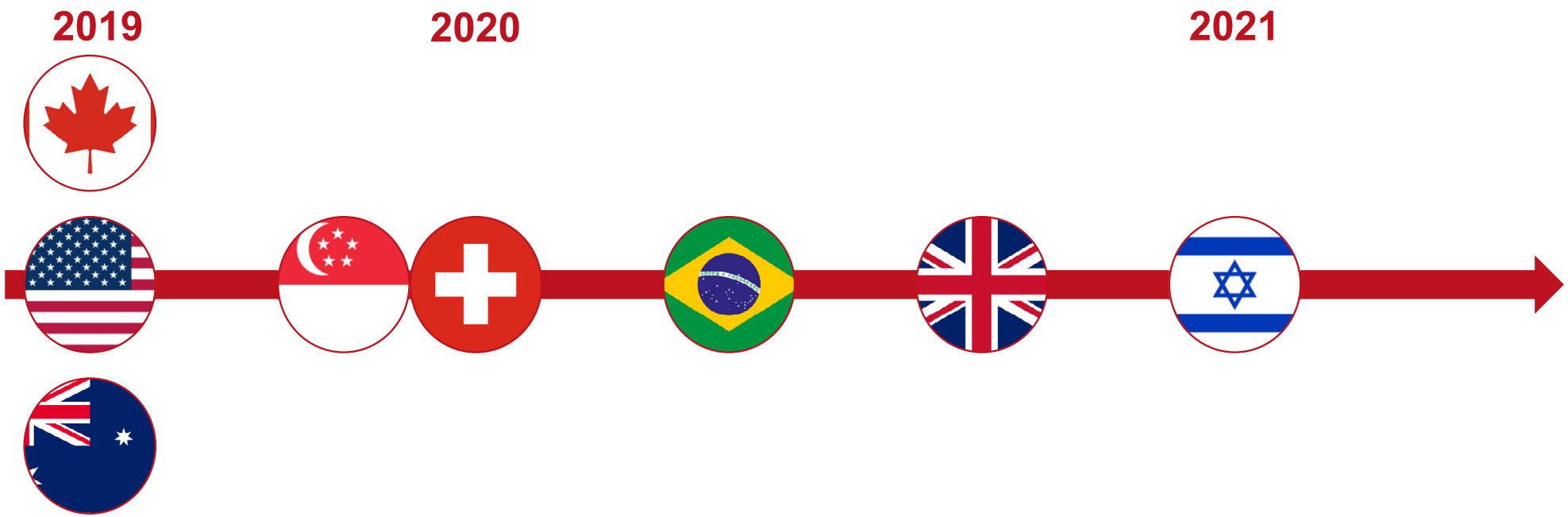
Regulatory Assessment

Context and objectives of Project Orbis

- **History**
  - FDA's Oncology Center of Excellence initiated Project Orbis in 2019
  - Framework for **concurrent submission and review of oncology products** among international partners
- **Main Objective**
  - Reduce the **submission gap** and shorten the **review time**
  - **earlier access** to oncology therapies for patients

Project Orbis Partners (POPs)



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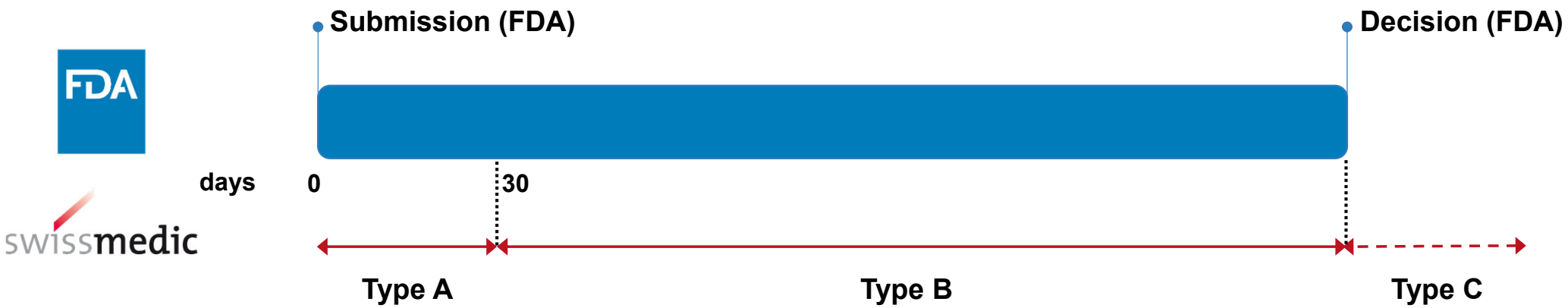
Orbis review types (Swissmedic)

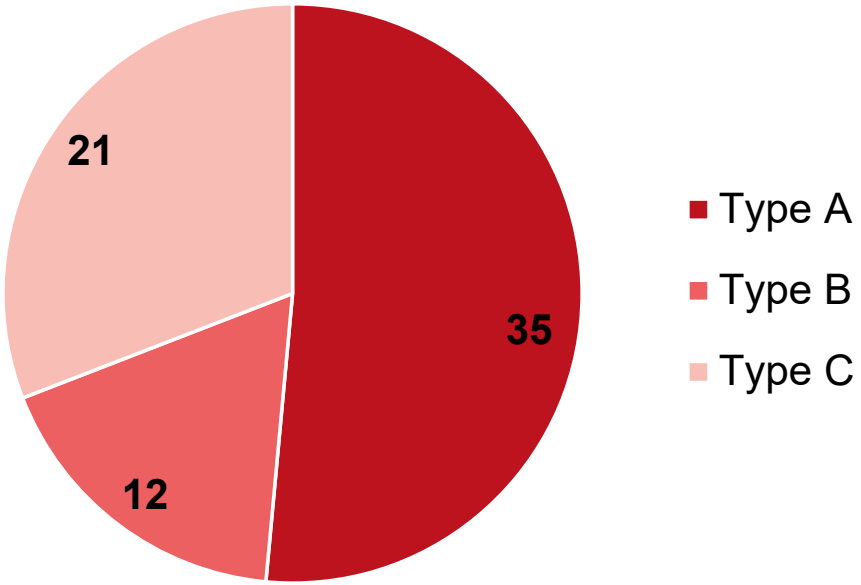


Achievement and Impact of Project Orbis

23 submitted NAS applications

45 submitted IE applications

Project Orbis Applications by Review Type (2020 – June 2024)



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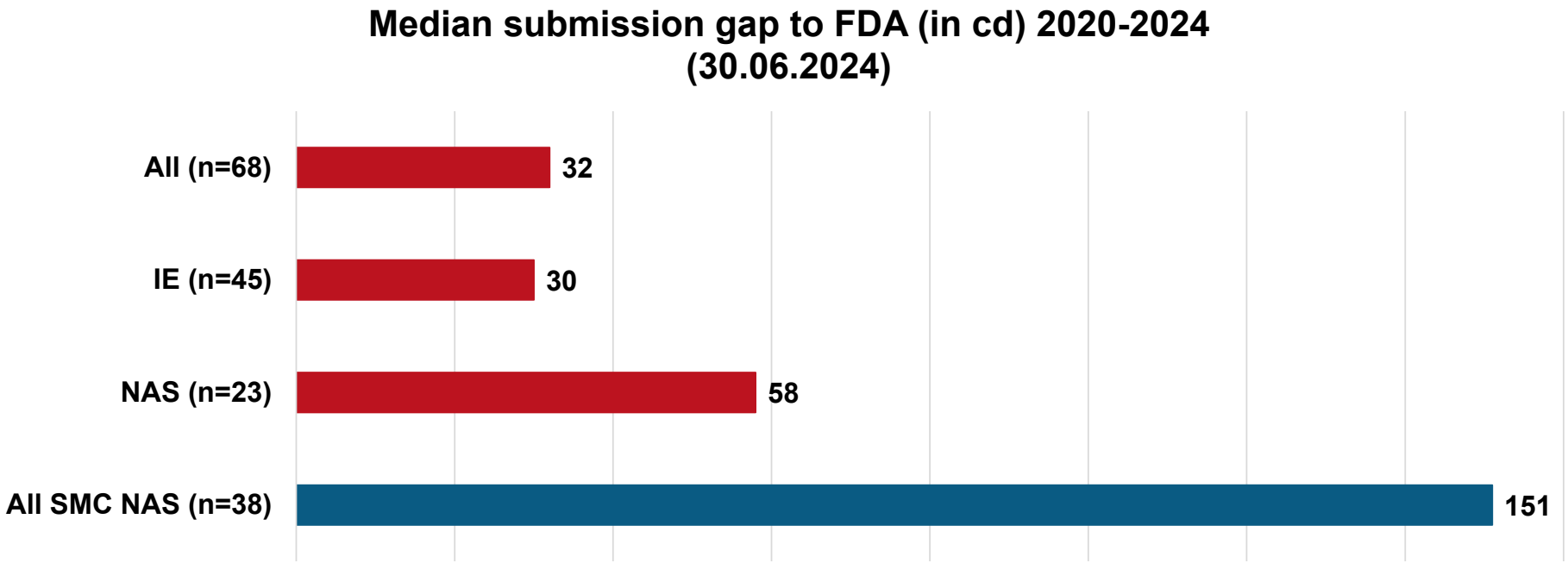
Achievement and Impact of Project Orbis



Median submission gap for all NASs approved at Swissmedic between 2019-2023: **151days** (n=38)

Benefits of Project Orbis

- Faster access to innovative treatments
- Long-term impact on access to new oncology therapies

- Strengthening of international cooperation and global recognition
- Sharing expertise

- Early market access
- Closer collaboration with Swissmedic

Future perspectives

- Achieve optimal efficiency in Switzerland
  - Improve **transparency** of the process (publication of the maximum timelines)
  - Continual **optimisation of the procedure** in Switzerland
  - Enhance **communication** between POPs – Swissmedic – Applicant

- Overcoming the challenges of **harmonising procedures** in the different participating countries
- Developing the **supporting technology** needed to simplify procedures.

Contact and links

- Contact:
  - ProjectOrbis@swissmedic.ch

- Links:
  - Project Orbis (Swissemdic.ch)
  - Project Orbis (FDA.gov)

- Latest publications :
  - Effect of Project Orbis participation by the Swiss regulator on submission gaps, review times, and drug approval decisions between 2020 and 2022: a comparative analysis, Zosso-Pavic, Matea et al., The Lancet Oncology, 25 (6), 770 – 778.
  - Index of Application Status Transparency and Availability of Public Information for Project Orbis Agencies, Lee, Sso H. et al., International Journal of Drug Regulatory Affairs,12 (3), 55-65.