swissmedic
20 Jahre 2002 - 2022

International Cooperation
Project Orbis und Access

Chantal Walther, Leiterin Einheit 4, Regulatory Assessment
Cornelia Bigler, Stv. Leitung Einheit 4, Regulatory Assessment

Collaboration amongst agencies ?

Review > Clin Pharmacol Ther. 2020 Mar;107(3):507-513. doi: 10.1002/cpt.1617.
Epub 2019 Oct 24.

Are the European Medicines Agency, US Food and Drug Administration, and Other International Regulators Talking to Each Other?

Tania Teixeira [1], Sandra L Kweder [2], Agnes Saint-Raymond [1]

Affiliations + expand

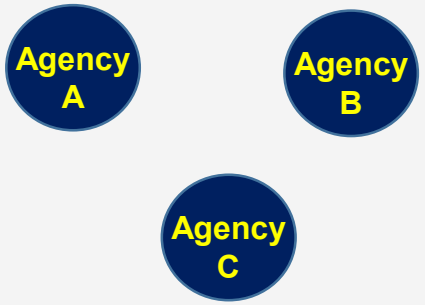
PMID: 31449664 PMCID: PMC7028217 DOI: 10.1002/cpt.1617

International Regulatory Agencies Collaborations

Medical Product Review Concepts of leading agencies

Past

Cluster Collaboration Concept



Present

Parallel Review Concept

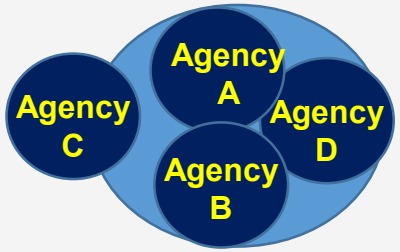
Prototype for Cancer

PROJECT ORBIS

Faster Patient Access

2019

Reliance Concept



Prototype for all Disease Areas

ACCESS CONSORTIUM

AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Work Sharing
between Agencies

Collaborations match Swissmedic Strategic Objectives

«Time-critical processes are accelerated»
(..Expectation of patients…fast authority)

«Reliance on results of other authorities
and work sharing»

Prototype for Cancer

PROJECT ORBIS

Faster Patient Access

Prototype for all Disease Areas

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Work Sharing
between Agencies

Swissmedic (SMC) and Project Orbis

«Time-critical processes are accelerated»
(..Expectation of patients…fast authority)

Prototype for Cancer

PROJECT ORBIS

Faster Patient Access

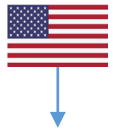
2020 2021 2022

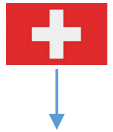
Pilot Phase

Full SMC process Implementation?

When is Orbis successful for Swissmedic?

Faster Patient Access to innovative Cancer Treatments





swissmedic

No Orbis

Submission Gap	Drug Assessment

Availability for Swiss Patients

PROJECT ORBIS

Subm. Gap	Drug Assessment

FASTER Availability for Swiss Patients ??

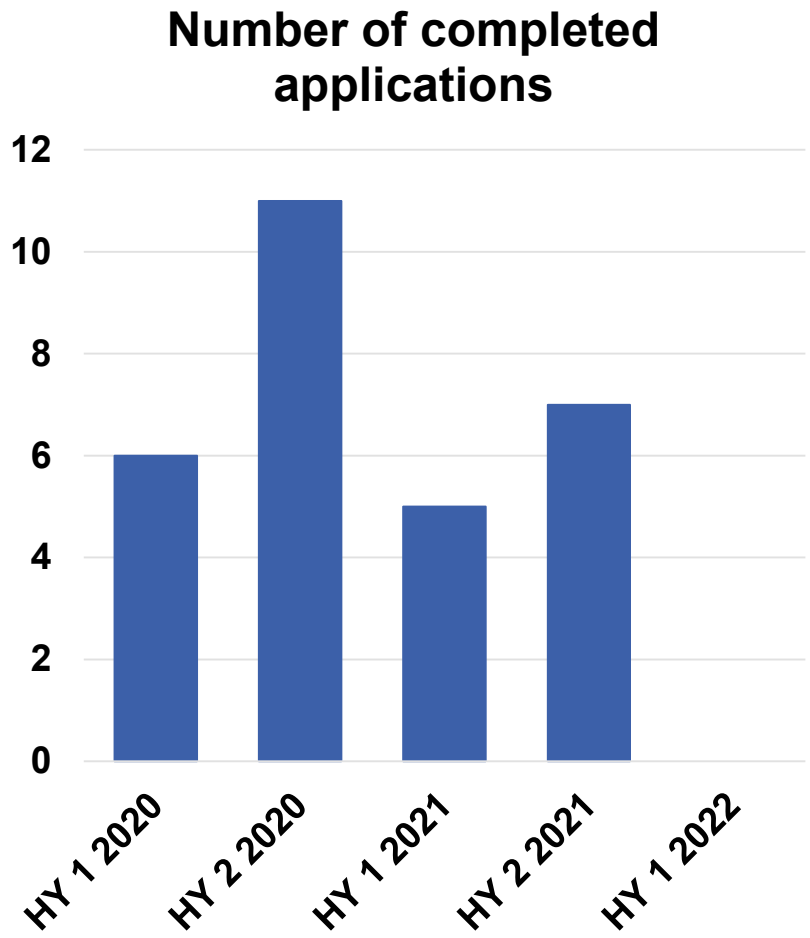
Orbis 2.5-Years Update 7/2022: 41 submissions

PROJECT ORBIS

Completed (29) : 8 NAS, 21 IE

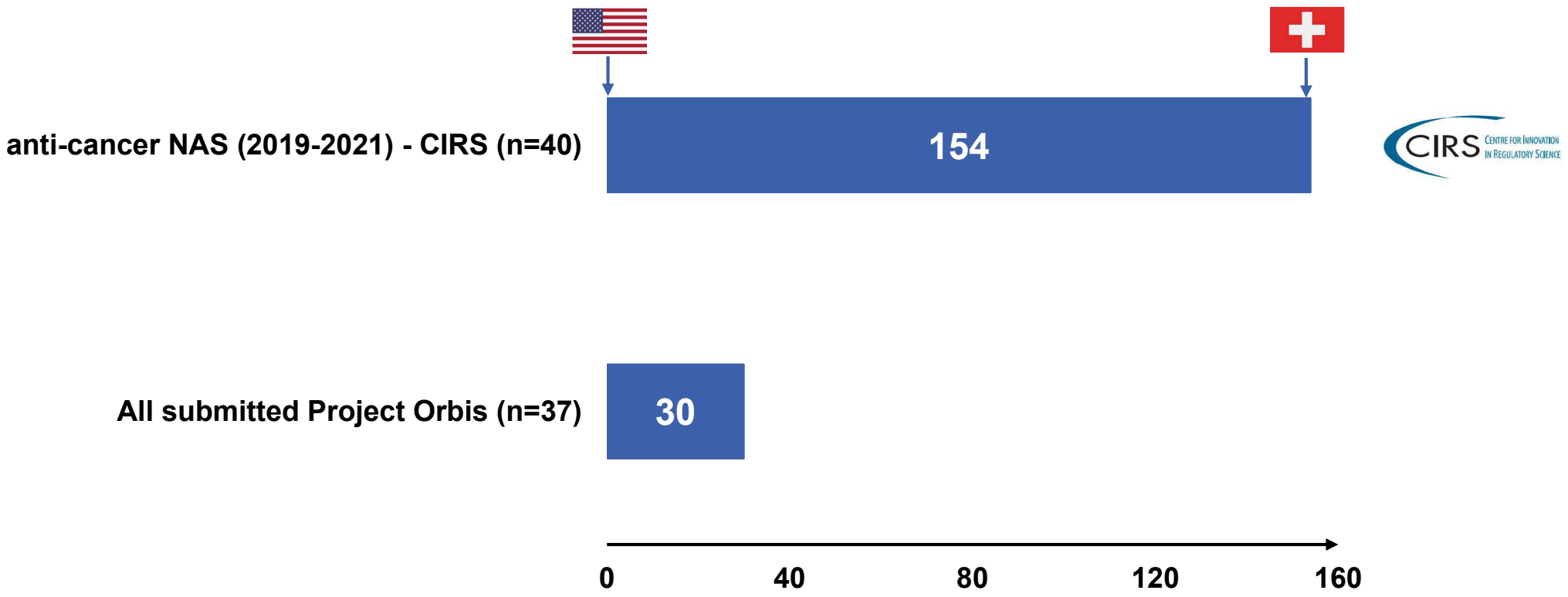
In Assessment (8) : 3 NAS, 4 IE

Accepted (4) : 3 NAS, 1 IE

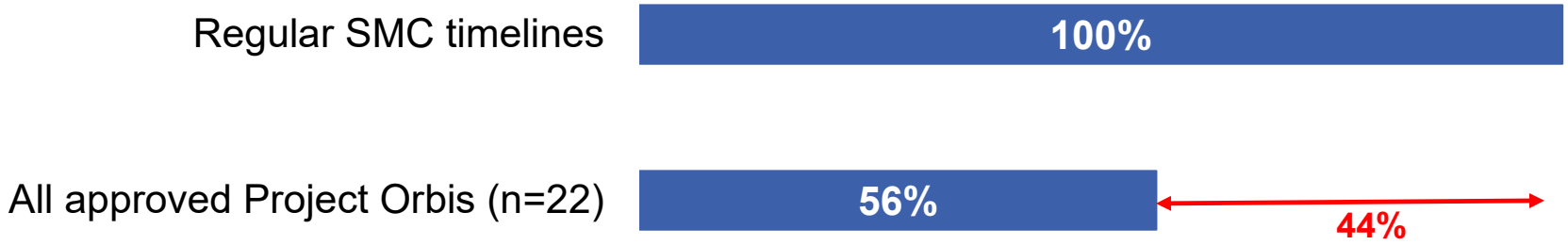


*NAS=New Active Substance, IE=Indication Extension

Reduction of Swiss Submission Gap

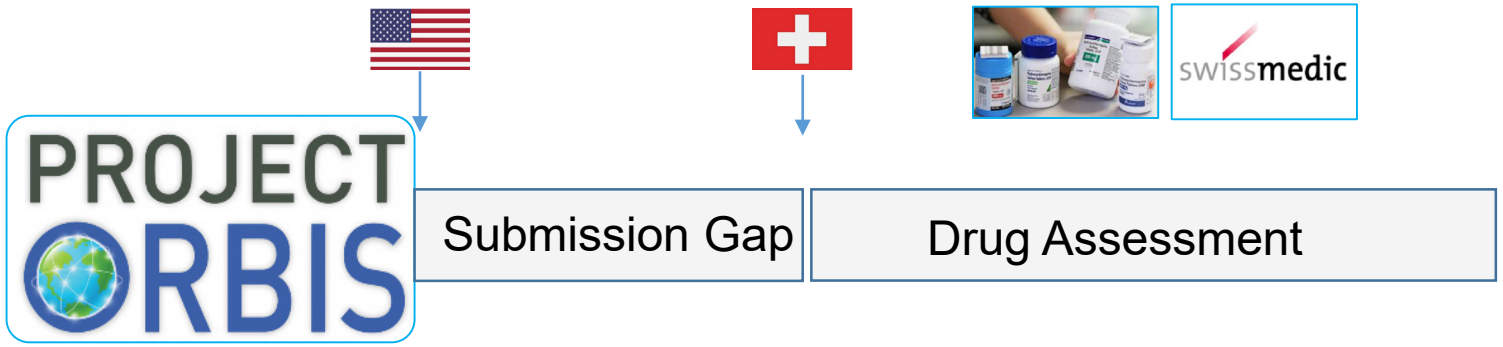


Reduction of Assessment time via Orbis (N=22)



Orbis is successful for Swissmedic

Faster Patient Access to innovative Cancer Treatments



FASTER Availability for Swiss Patients

2021 → 2022

Full Implementation to SMC processes

Swissmedic and Access Consortium

Prototype for Cancer

PROJECT ORBIS

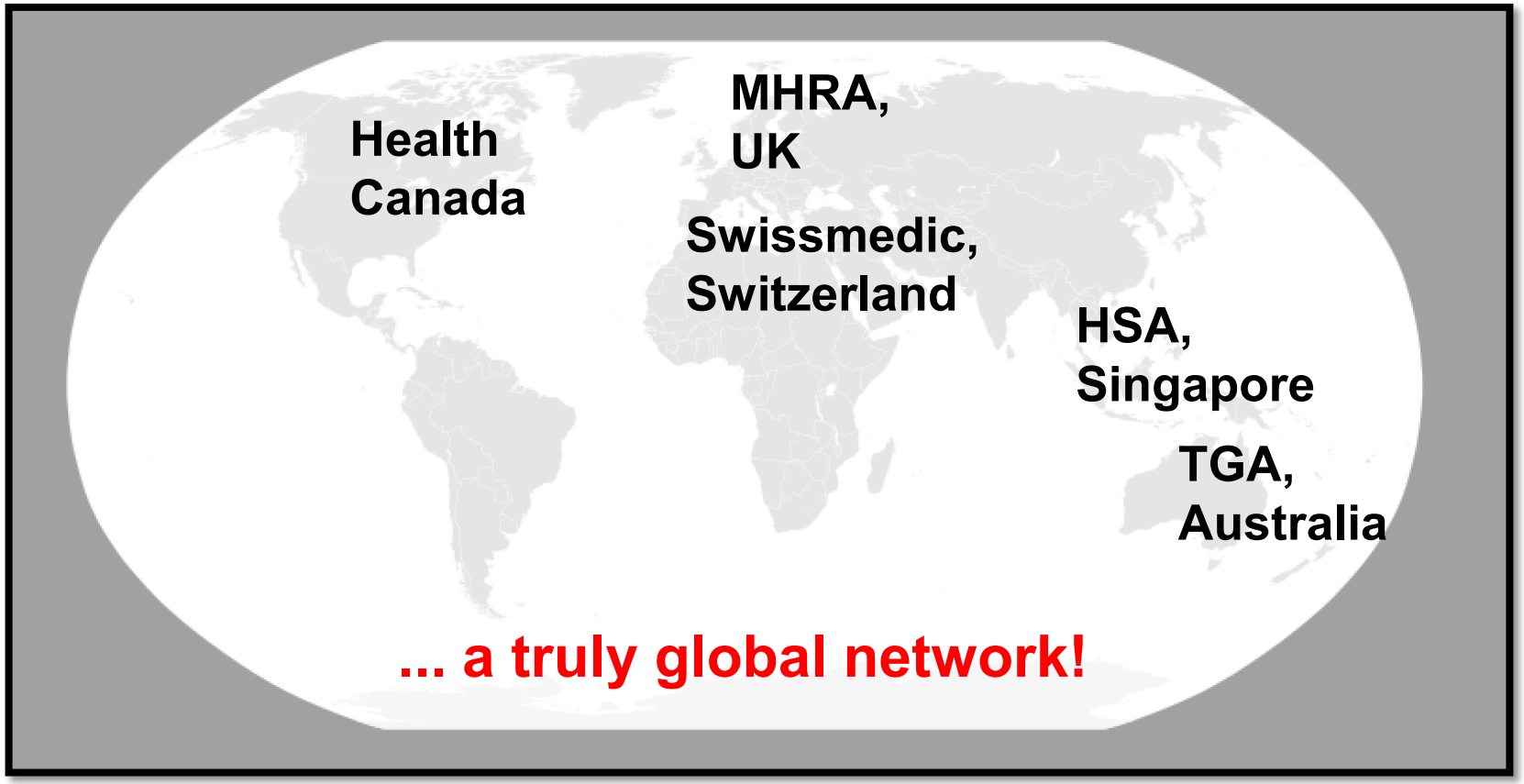
Faster Patient Access

Prototype for all Disease Areas

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Work Sharing
between Agencies

Access Consortium



Access Strategic Plan 2021-2024

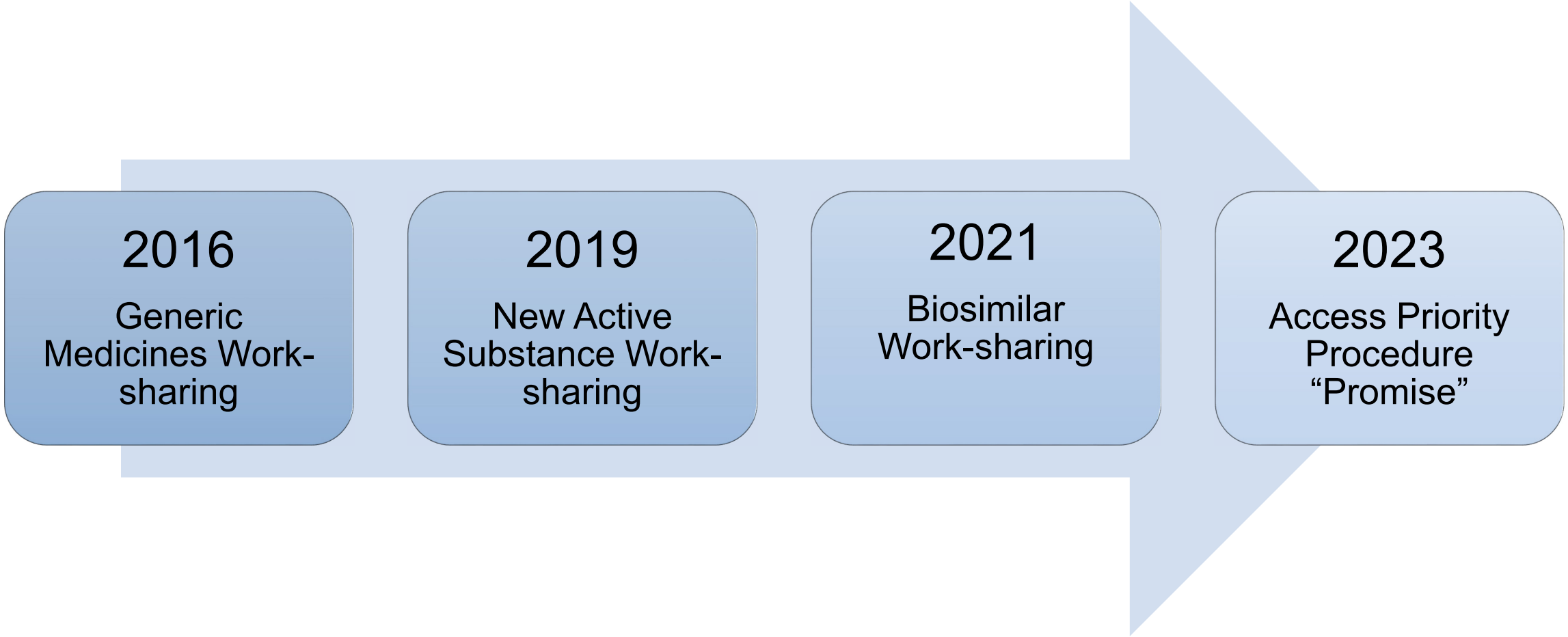
- **Vision**

Our vision is to provide **faster access** to safe, effective and high quality medicines for all our populations.

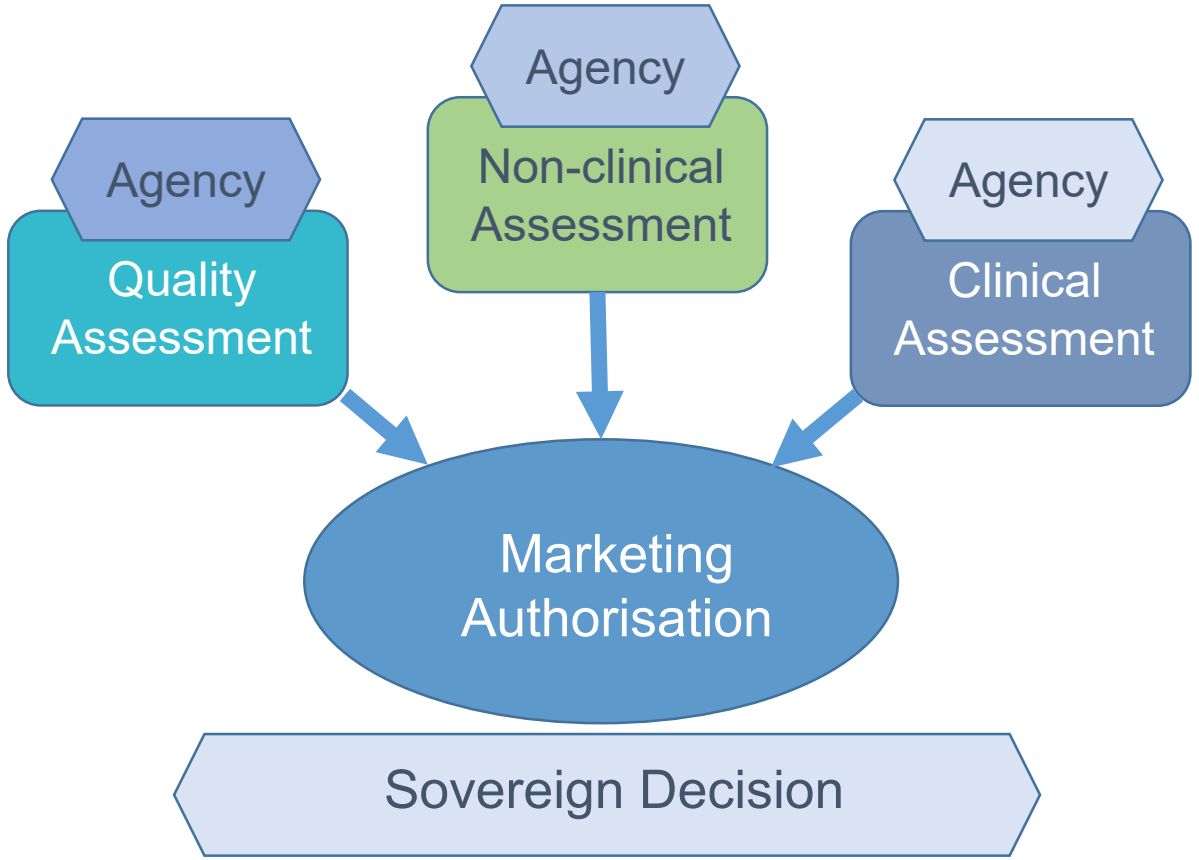
- **Strategic Objectives**
  - Strengthening Access work-sharing initiatives
  - Expanding lifecycle approach
  - Regulatory innovation that integrates a healthcare systems approach

Access Working Groups (WG)

Swissmedic and Access Work-sharing



New Active Substance Work-Sharing Initiative (NASWSI)



Requirements NASWSI

- Simultaneous submission to at least two of the Access Consortium Agencies

- New active substance application OR
- New indication application

- Identical datasets for Modules 2-5
- Country-specific Module 1

Role determination for Access partners

- NASWSI: Agencies consider their operational needs when allocating review responsibilities

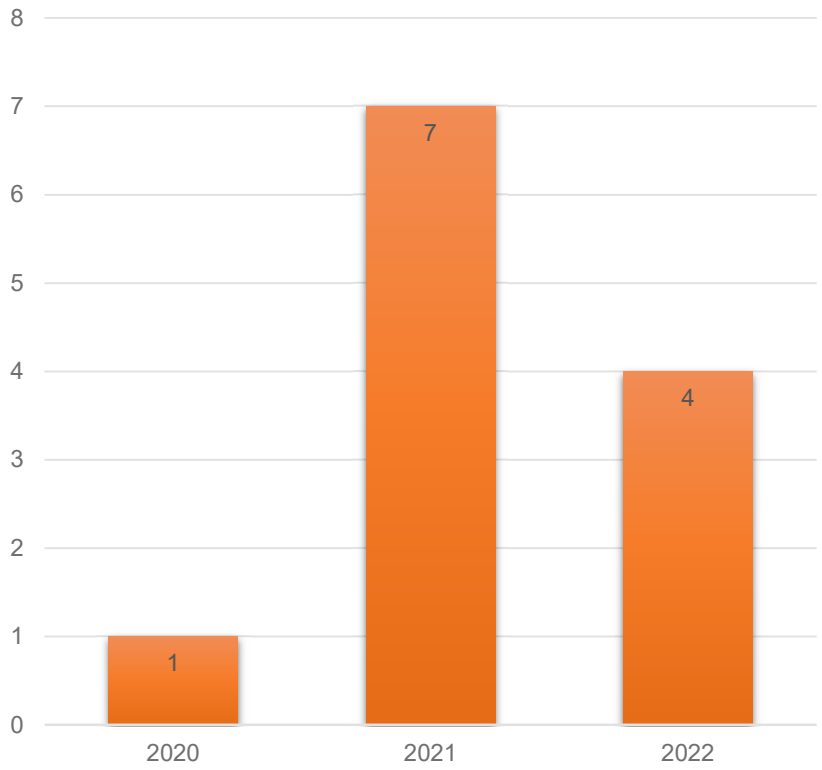
- GMWSI (Generic Work-Sharing Initiative): Applicant can propose a Lead Agency

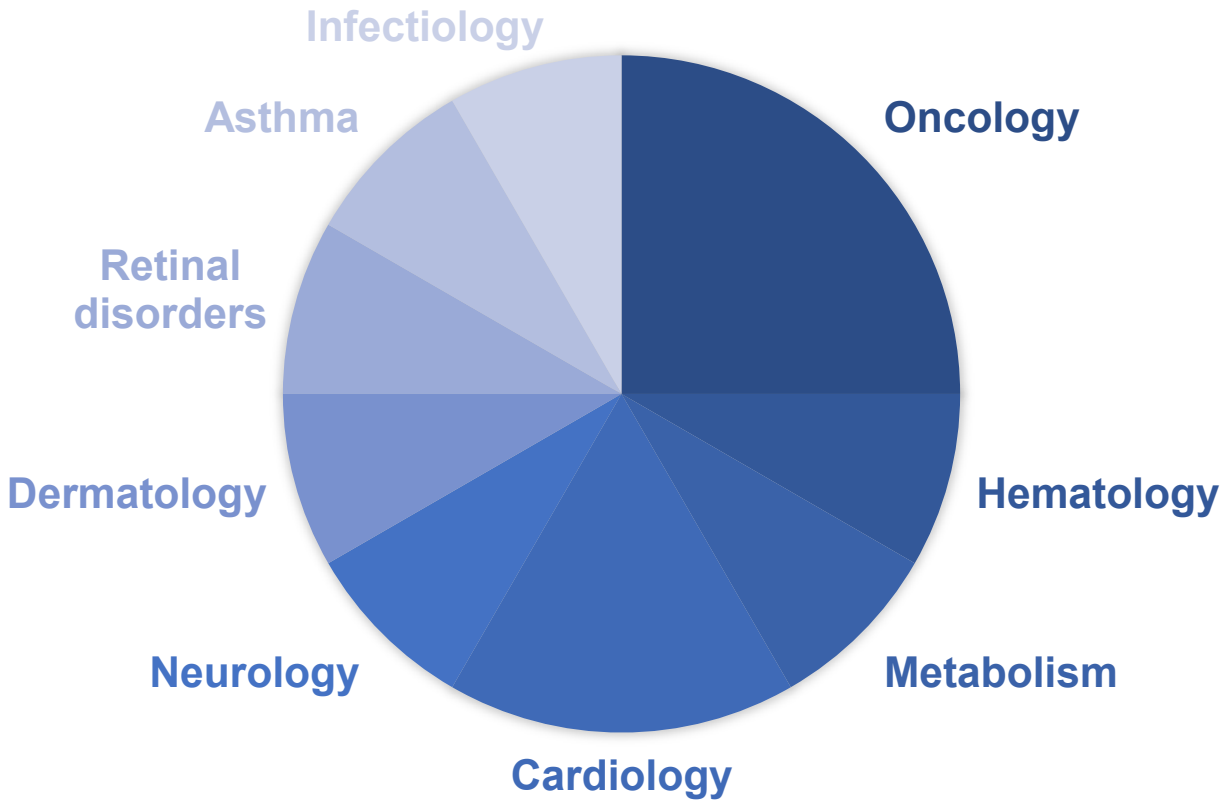
NASWSI Applications at Swissmedic April 2019 - July 2022

- Completed (12)
- In Assessment (6)
- Pipeline (3)

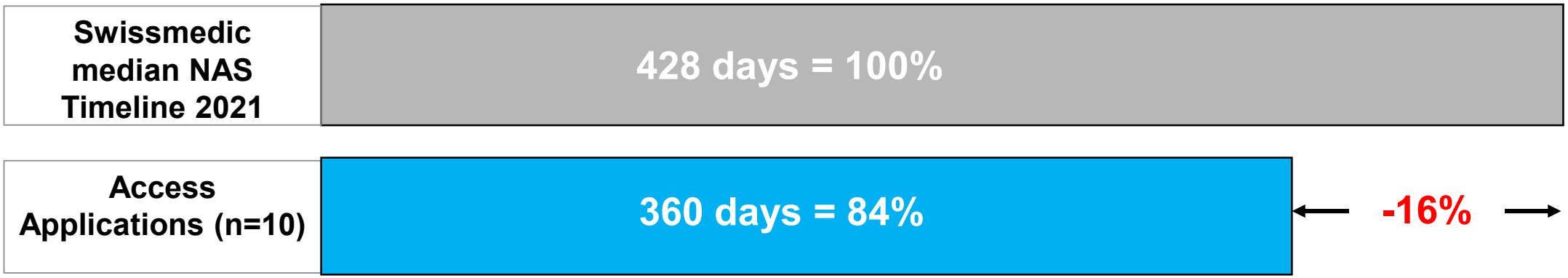
N=21 (18 New active substances, 3 indication extensions)

Completed applications until 07/2022

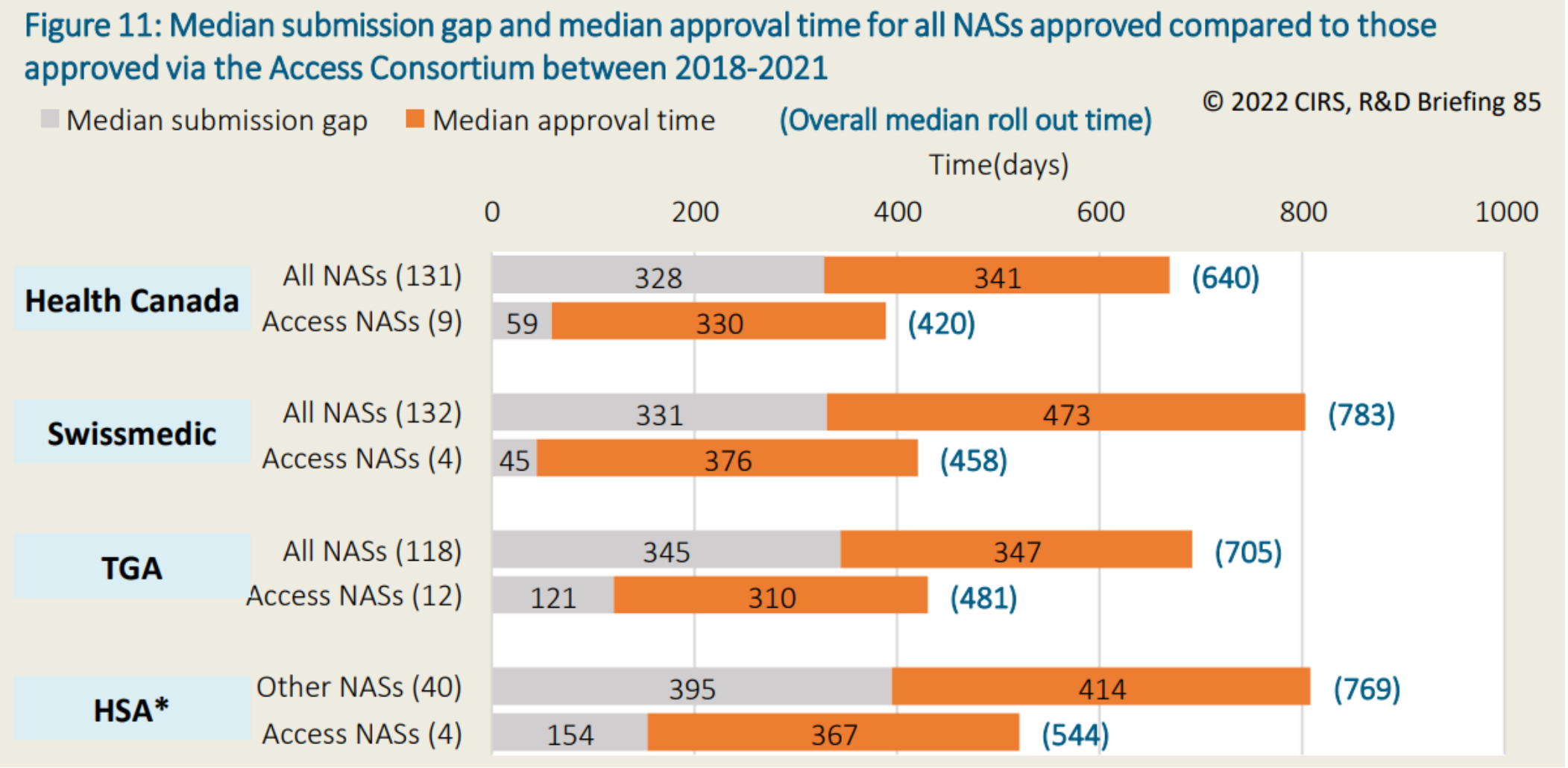




Reduction of Assessment time via Access NASWSI (N=10)



CIRS: Access applications submission gap and approval time



Summary : Swissmedic View

Successful Collaborations : to be continued in future !

Prototype for Cancer

PROJECT ORBIS

Faster Patient Access

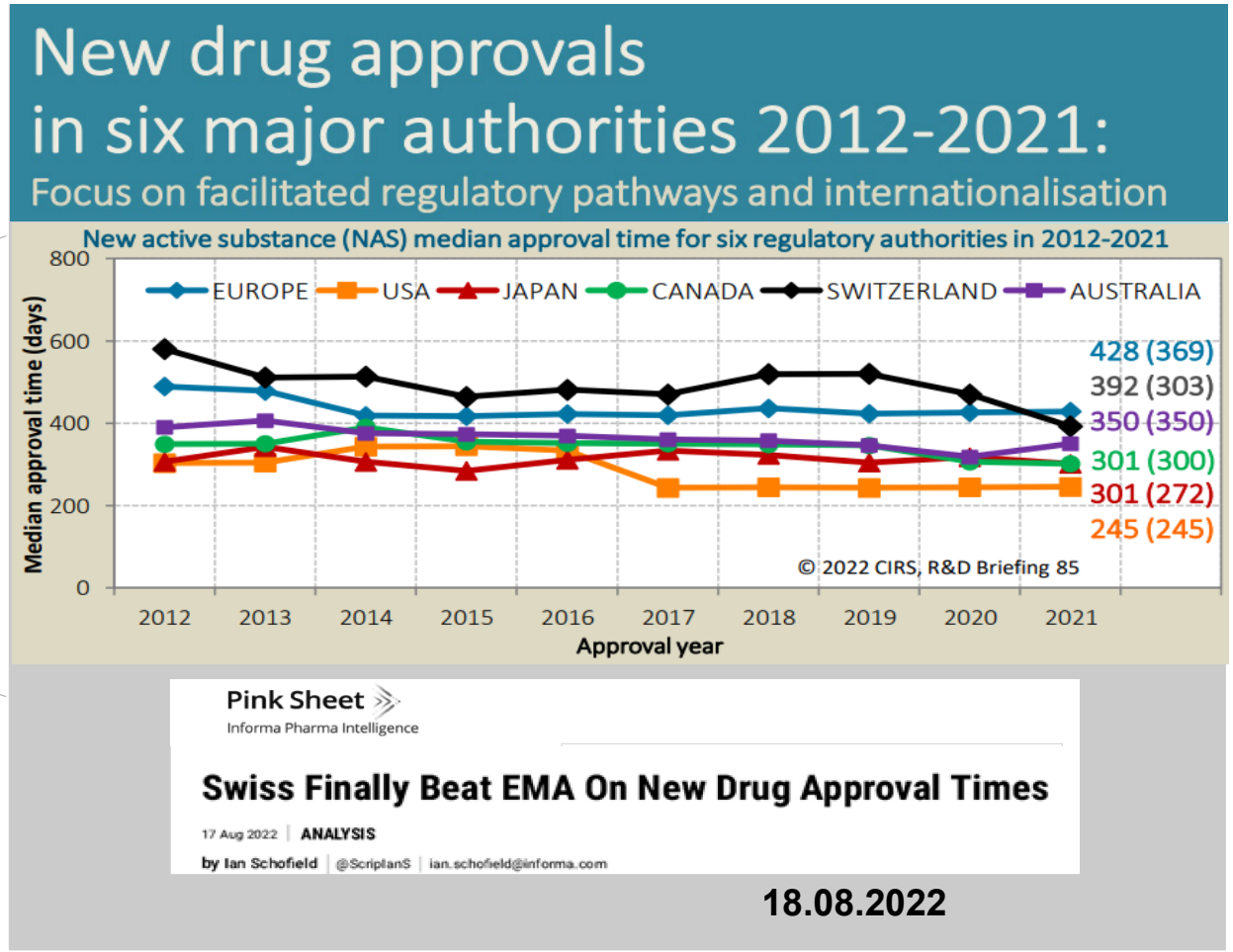
Prototype for all Disease Areas

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Work Sharing between Agencies

Summary : Swissmedic View

Successful Global Collaborations and Impact



Advice for applicants

- Good internal communication
- Well structured submissions
- Close exchange with authorities

Weitere Informationen

Orbis

- Swissmedic approves first new active substance as part of Project Orbis
- Project Orbis: findings after the first year (swissmedic.ch)
- Swissmedic permanently involved in Project Orbis

Access

- Access Consortium (swissmedic.ch)
- NASWSI Operational procedures
- Access Strategic Plan 2021-2024
- International cooperation on therapeutic products (swissmedic.ch)

Centre for Innovation in Regulatory Science (CIRS) Briefing

- R&D Briefing 85 28 June 2022
- Authorisations of human medicinal products with a new active substance and additional indications 2021 (swissmedic.ch)

Access Work-sharing: Pros & Cons for the pharmaceutical industry

- ✓ Strengthening and expanding international cooperation
- ✓ Evaluation plan specified in advance
- ✓ A less time-consuming procedure thanks to the submission of a joint dossier
- ✓ Consolidated List of Questions*
- ✓ Shorter timelines
- ✓ Simultanous market access in several countries
- ✓ Opportunity to make a contribution to innovation in the area of regulation

- ✗ Coordination across several time zones
- ✗ Increased coordination efforts for affiliates

*Country-specific questions still possible

Access Work-sharing: Pros & Cons for Swissmedic

- ✓ Reduced workload due to splitting review/ modules between agencies
- ✓ Sharing of resources and expertise across jurisdictions
- ✓ Positioning of Swissmedic as 1st-wave-agency
- ✓ Faster access for patients in CH

- ✗ Coordination across several time zones
- ✗ Increased coordination efforts for Regulatory Assessment