Health Canada and International Collaboration Initiatives

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Disclaimer

The views expressed in this presentation are those of the authors and not necessarily those of Health Canada.

This presentation is incomplete without accompanying verbal commentary.

I have no conflicts to declare.

Presentation Outline

- International collaboration in the Health Canada - Health Product and Food Branch
- ORBIS project overview
- ACCESS Consortium overview
- Look forward perspective

Health Canada as a Global Regulator

- We engage **internationally both bilaterally and multilaterally** to help us achieve our goals and provide leadership and key contributions on the world stage.

- Regarding **health products**, we maintain strong working relationships with key partners – US, EU, the UK, Australia, Singapore, and Switzerland given our policy and regulatory alignment, to **enhance our drug approval process.**

- Regarding **food safety**, we build and maintain strong working relationships with key partners with mature food safety systems – US , EU, Australia and New Zealand – as well as at the Codex Alimentarius Commission to support risk management, policy and regulatory development, align scientific approaches, and **maintain our world class food safety systems.**

FDA U.S. FOOD & DRUG ADMINISTRATION

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS
Food and Agriculture Organization of the United Nations
World Health Organization

Working Collaboratively with Trusted Partners

IMPROVING ACCESS TO DRUGS, MEDICAL DEVICES, AND MAINTANING ACCESS TO SAFE FOOD

International Drug Review Collaboration

Project ORBIS

ACCESS Consortium

EMA Open

Bilateral Engagement

Veterinary Drugs parallel reviews with FDA

HC-Food Standards Australia New Zealand collaboration

Multilateral Engagement

Codex Alimentarius

International Coalition of Medicines Regulatory Authorities

Regulatory Alignment

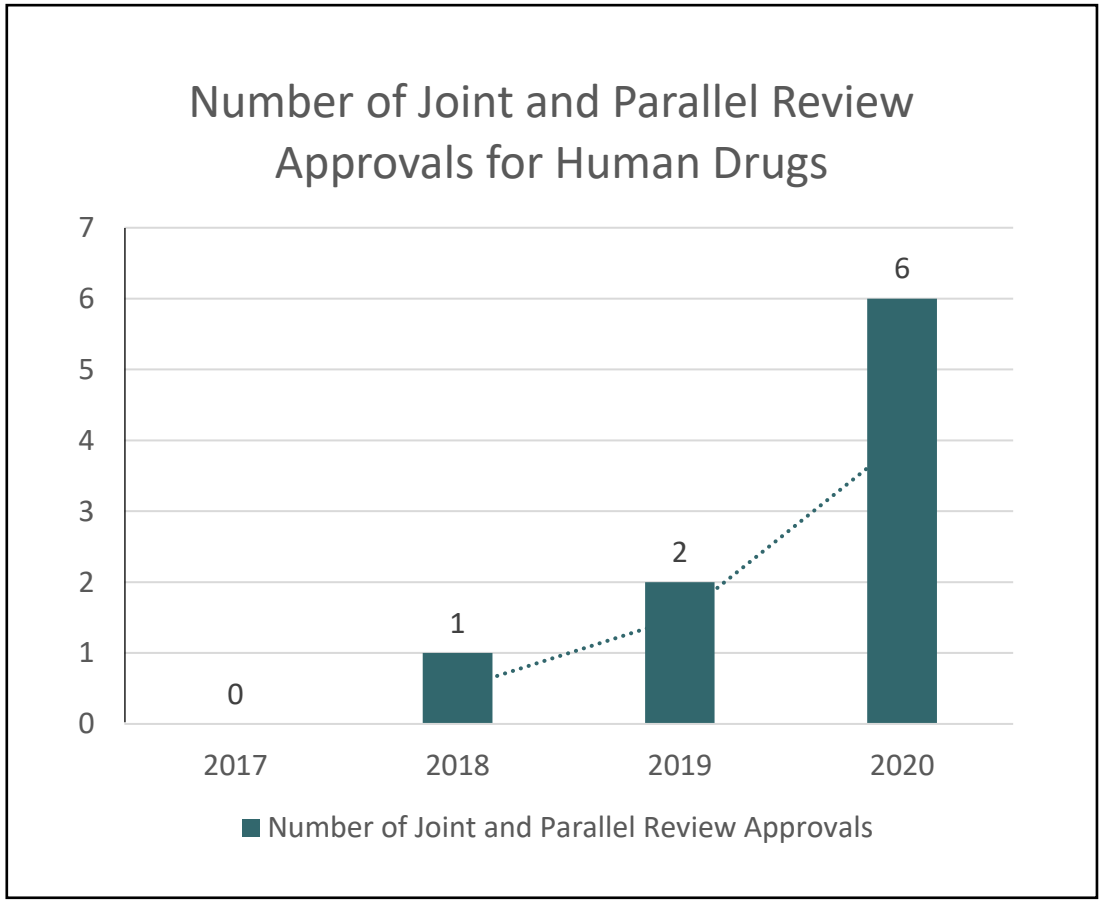
Medical Device Single Audit Program

International Council on Harmonization

Information Sharing

40 Confidentiality Arrangements with 23 countries including 4 multilateral organizations

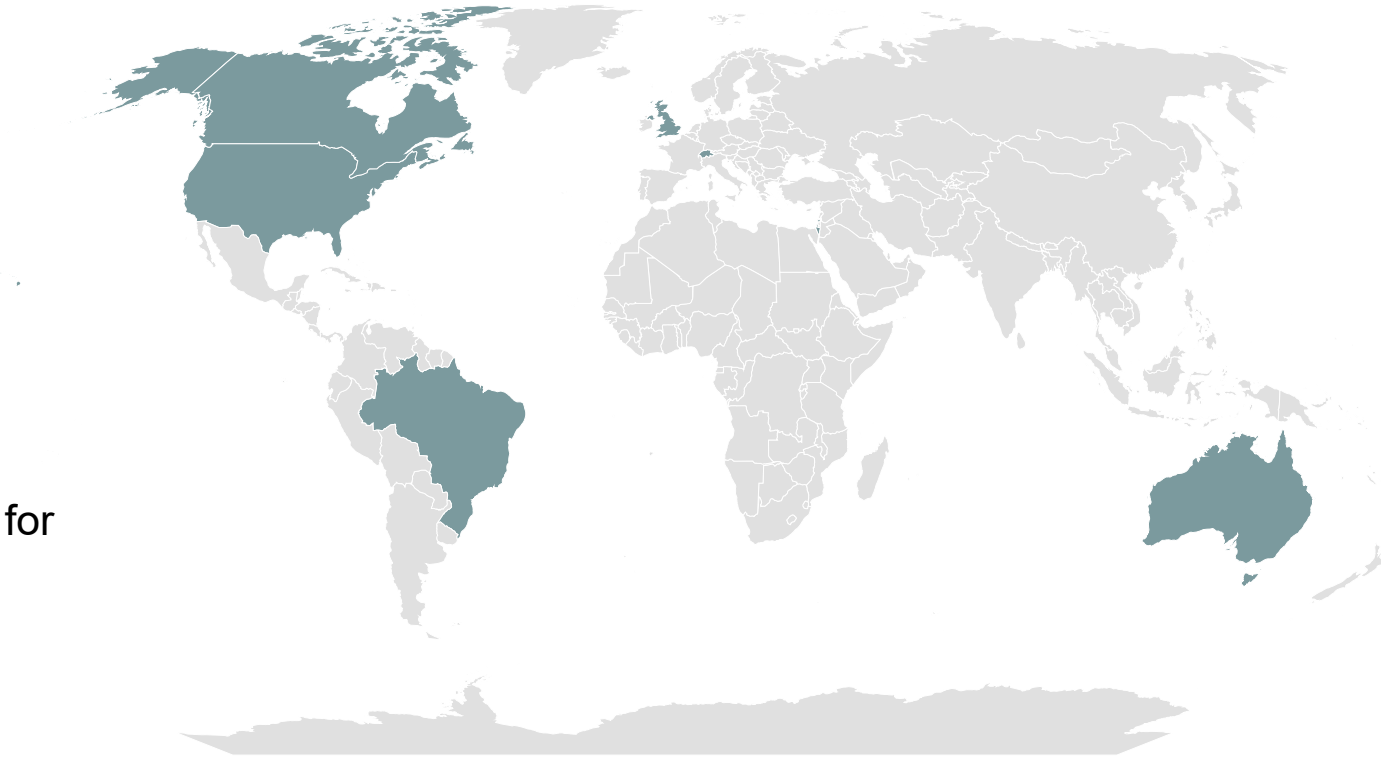
Collaborative Reviews Circa 2021



Eight years ago, we largely relied on our own analysis to review health products. We are now collaborating more internationally on reviews and approvals, which results in **accelerating access to innovative drugs for Canadians.**

Project ORBIS

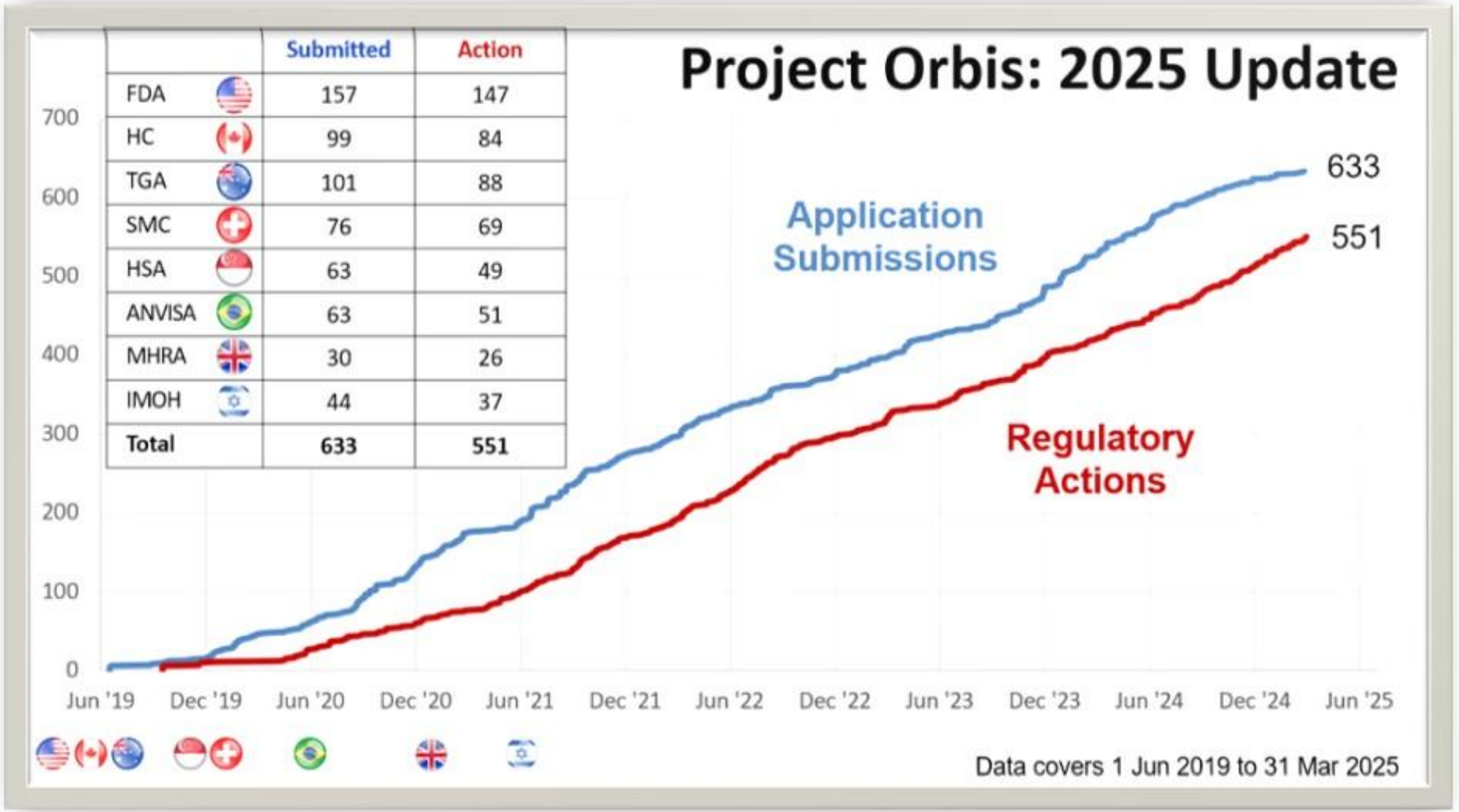
- Discussion of timelines between regulators and company during pre-submission orientation discussions
- Facilitates submission and review of oncology marketing applications.
- Real-time sharing of IR and their responses.
- Each country retains independent decision-making for each application.
- Possible common meeting that can be attended by Project ORBIS partners:
    - FDA Applicant Orientation Meeting.
    - ORBIS Kickoff Meeting.
    - FDA Mid-Cycle Meeting.
    - FDA Labelling meetings.



Project ORBIS: Types

ORBIS Type	Submission Timeline	Submission overlaps with FDA	Sharing of FDA reviews	Multi-country review meetings (POP TCONs)	POP Attendance at FDA review meetings	Concurrent review with FDA	Near concurrent action with FDA
Type A	Application submission to POPs ≤ 1 month of FDA submission	Expected	Yes	Yes	Yes	Expected	Possible[1]
Type B	Application submission to POPs > 1 month of FDA submission	Expected	Yes	Yes	Yes	Possible	No[1]
Type C	Any time after FDA submission[2]	Permitted[2]	Yes	No	Unlikely	Unlikely	No[1]

[1] Regulatory action in other jurisdictions is unlikely to occur immediately after FDA action and will follow respective health authority timelines.
[2] Dependent on Project Orbis Partner (POP) guidelines. Contact specific POP(s) regarding optimal timing for submission of Type C dossier.



Source: Dr Angelo DeClaro, Division Director CDER, FDA

Project ORBIS: Statistics

YEAR	TYPE A	TYPE B	TYPE C	TOTAL
2019	0	0	0	0
2020	3	0	0	3
2021	3	2	6	11
2022	1	1	6	8
2023	0	1	2	3
2024	2	1	2	5
2025*	0	2	0	2
Total	9	7	16	32

NDS = New Drug Submission

YEAR	TYPE A	TYPE B	TYPE C	TOTAL
2019	3	0	0	3
2020	3	1	0	4
2021	3	6	0	9
2022	4	6	4	14
2023	2	1	5	8
2024	4	2	4	10
2025*	0	4	0	4
Total	19	20	13	52

SNDS= Supplement to a New Drug Submission

- Yearly submission number ranged from 2-11 NDSs and 3-14 SNDSs.
- PO-Type A were favored during the pilot phase.
- In recent years, a more even distribution among the 3 PO types has emerged.

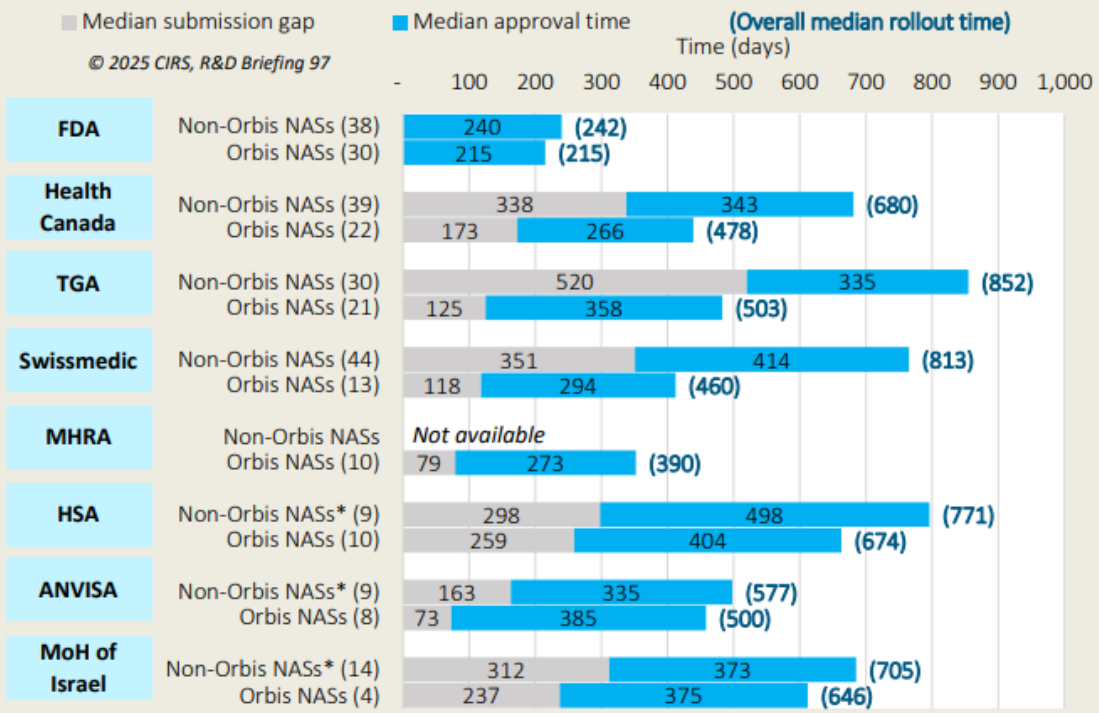
Project ORBIS: Statistics

Current submissions in active review (NDS and SNDS)	In review		Total
	PDD	BRDD	
Type A	3	0	3
Type B	2	5	7
Type C	3	2	5
Total	8	7	15

- Ongoing project number remains within the range from past years
- The distribution between drug classification and PO type remain within past range

Project ORBIS: Timelines

Figure 9. Comparison of median submission gap, approval time, and rollout time for NASs approved via Project Orbis vs. other non-Orbis NASs (2019-2023)

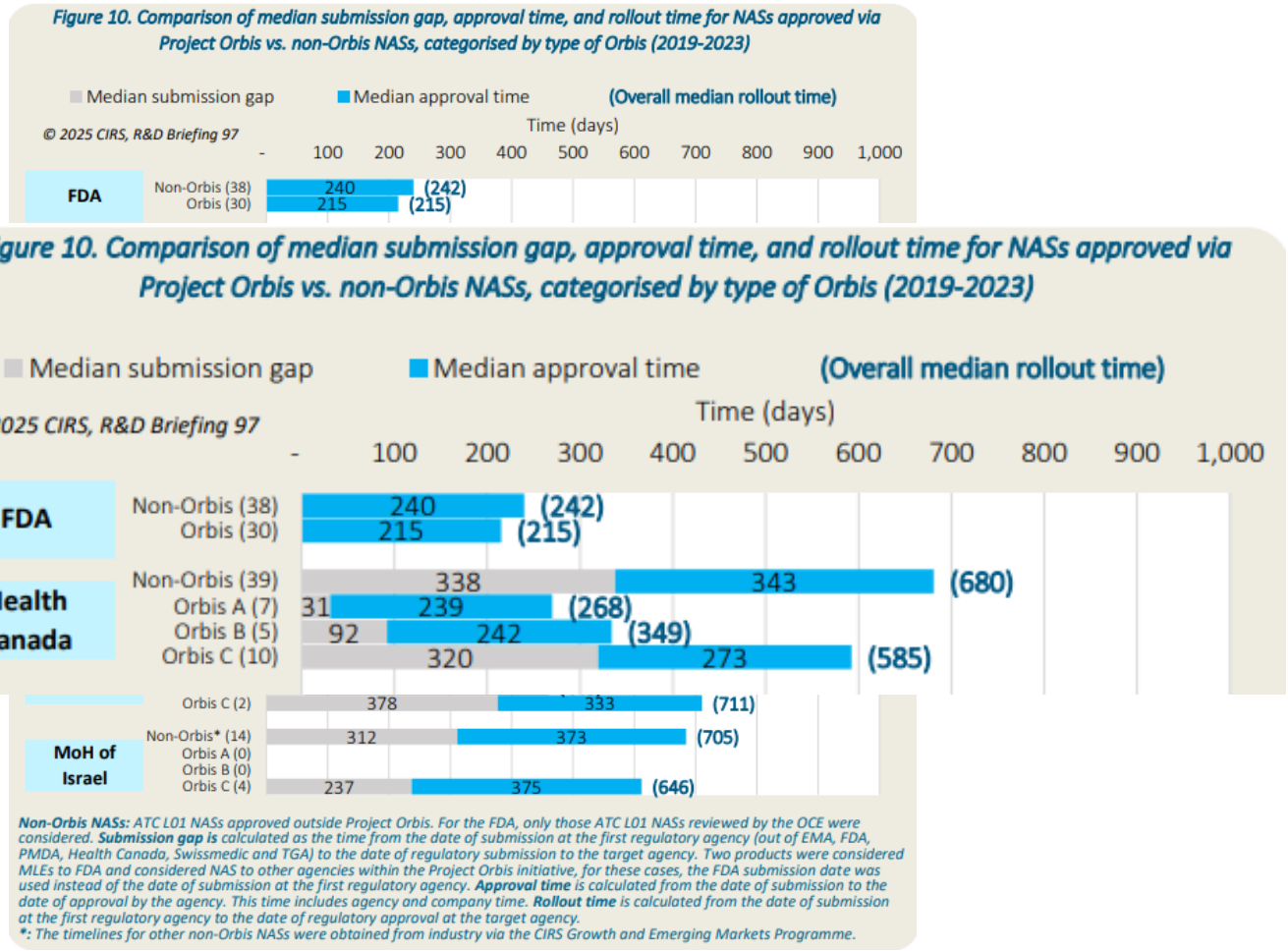


Non-Orbis NASs: *ATC L01 NASs approved outside Project Orbis. For the FDA, only those ATC L01 NASs reviewed by the OCE were considered.* ***Submission gap*** *is calculated as the time from the date of submission at the first regulatory agency (out of EMA, FDA, PMDA, Health Canada, Swissmedic and TGA) to the date of regulatory submission to the target agency. Two products were considered MLEs to FDA and NASs to other agencies within the Project Orbis, for these cases, the submission date of FDA was used instead of the date of submission at the first regulatory agency.* ***Approval time*** *is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.* ***Rollout time*** *is calculated from the date of submission at the first regulatory agency to the date of regulatory approval at the target agency.* *******: *The timelines for other non-Orbis NASs were obtained from industry via the CIRS Growth and Emerging Markets Programme*

- Median submission gap reduced by 165 days
- Median approval time reduced by 77 days

Source: Centre for Innovation in Regulatory Science (2024) R&D Briefing 97: Access Consortium and Project Orbis New Active Substance Approvals Across Eight National Regulatory Authorities. A Five-Year Comparative Study. Centre for Innovation in Regulatory Science. London, UK.

Project ORBIS: Timelines



- Median submission gap reduction is tied to the Project ORBIS type.
- Median approval time reduction also depends on Project ORBIS type and range from 70 to 104 days.

Source: Centre for Innovation in Regulatory Science (2024) R&D Briefing 97: Access Consortium and Project Orbis New Active Substance Approvals Across Eight National Regulatory Authorities. A Five-Year Comparative Study. Centre for Innovation in Regulatory Science. London, UK.

Project ORBIS Achievements

- A robust pipeline of new oncology drugs and new indications filed faster and approved faster in Canada.

- A strong and secure process by which regulatory agencies can discuss issues, share analyses and documents.

- A platform to find/discuss/appreciate differences in regulatory requirements, regulatory processes and timelines and foster convergence.

- A process that allows reduction of duplication of efforts from the sponsors and regulators perspectives.

ACCESS Consortium

https://accessconsortium.info/

ACCESS Consortium

- A coalition of **like-minded medium-sized** regulatory authorities
- Aims to promote **faster and broader access** to medicines by our population, **better align regulatory systems** and **reduce unnecessary duplication** and differences
- Meets regularly to **workshare** & exchange information on major regulatory issues/ challenges

Members

- Australia - Therapeutic Goods Administration (TGA)
- Canada - Health Canada
- Singapore - Health Sciences Authority (HSA)
- Switzerland - Swissmedic
- UK - Medicines and Healthcare products Regulatory Authority (MHRA)

Working Groups

- New Active Substance (NAS)
- Generic Medicines
- Clinical Trials
- Risk Management Plan
- Biosimilars
- Advanced Therapy Medicinal Products (ATMP)
- Complementary Health Products
- Patient Engagement
- IT Working Group

Mechanism & Benefits of ACCESS Work-sharing

ACCESS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND
UNITED KINGDOM

Mechanism

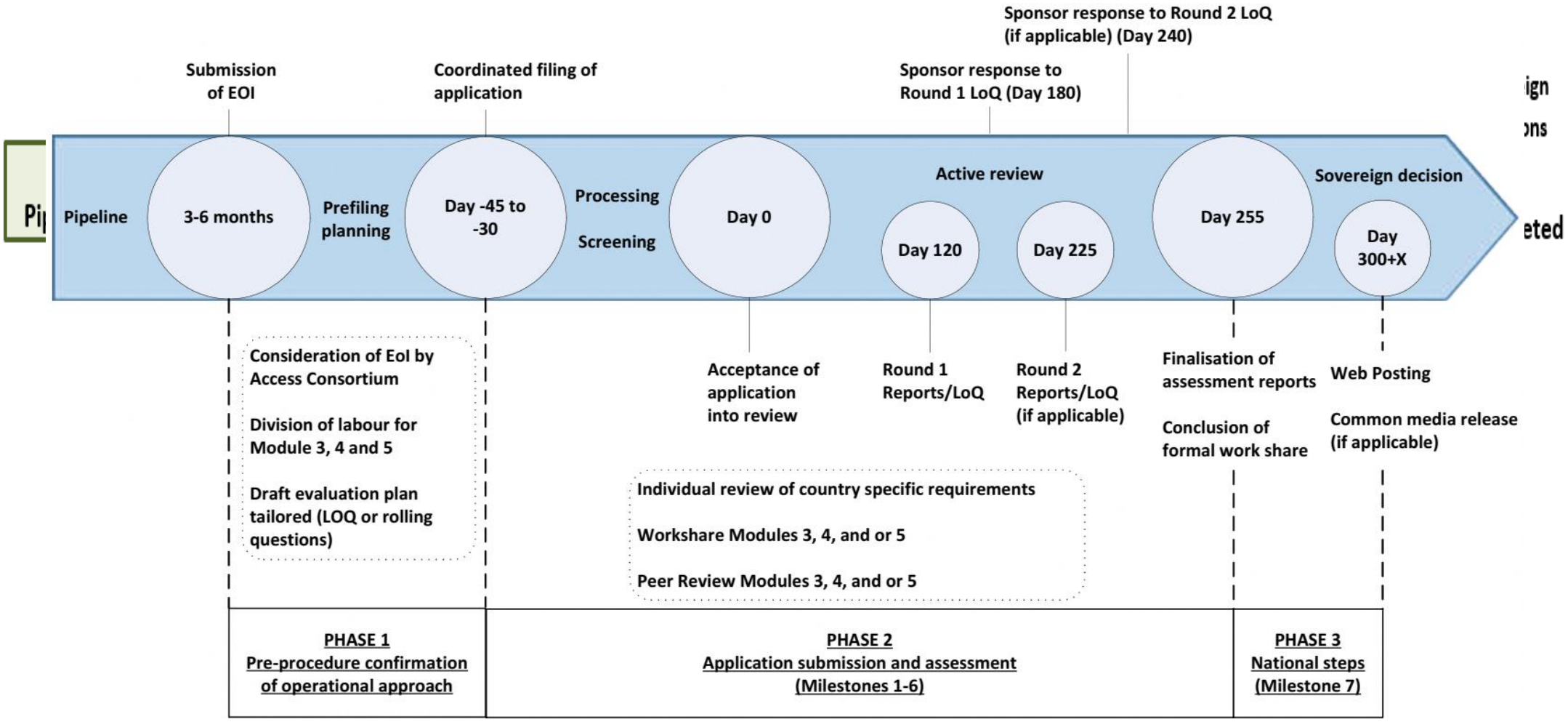
1. Advance notice via Expression of Interest
2. Joint submission to 2 or more of the 5 ACCESS regulators
3. Consolidated filing with common dossier
4. Consolidated Q&As from all regulators to which joint submission is made

Mechanism

1. Simultaneous coordinated review via work sharing among ACCESS agencies
2. Independent sovereign decision on final approval

Published **5** guidances/statements (including industry guidance and statements on Covid-19 vaccines & medicines and GMP Inspection Reliance)

ACCESS Procedure – Harmonisation Efforts



Source: ACCESS Consortium: Operational procedures for New Active Substances Work-Sharing Initiative (NASWSI)

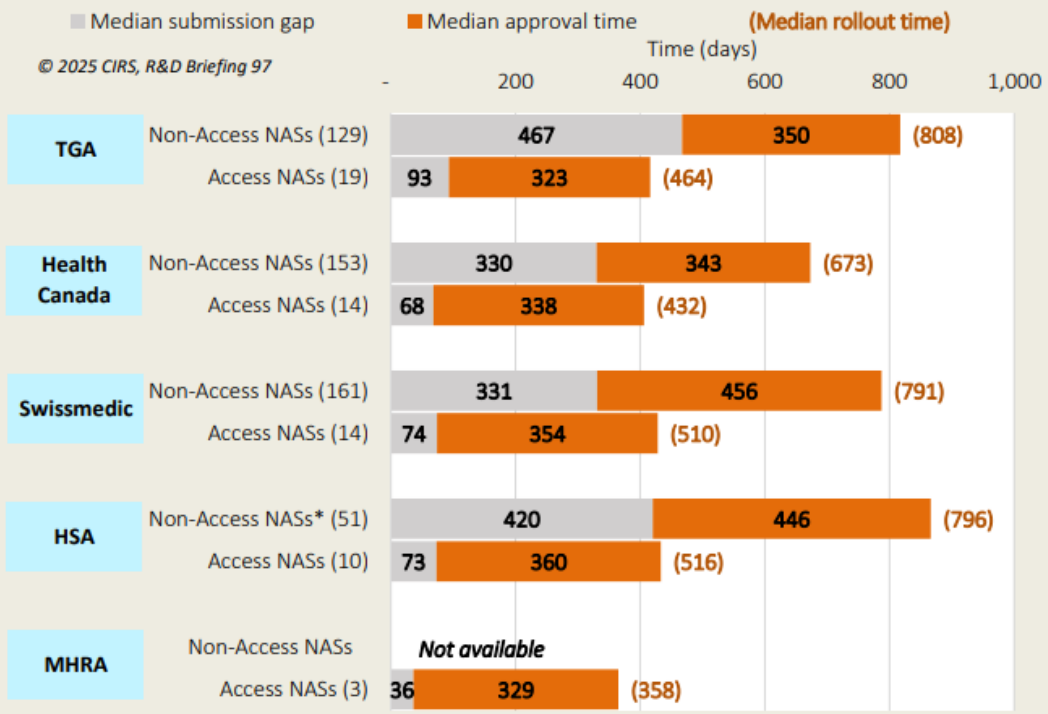
ACCESS Statistics

Transaction type	Quantity worked on by Health Canada*
Submissions pending	5
Submissions in active review	5
Submissions approved to date	**30**
Quantity of sovereign regulators participating in the 30 approvals*	
2-way collaboration	10
3-way collaboration	11
4-way collaboration	6
5-way collaboration	4

*Statistics are current as of October 02, 2024

Project ACCESS: Timelines

Figure 4. Comparison of median submission gap, approval time, and rollout time for NASs approved via Access Consortium vs. Non-Access NASs (2019-2023).



***Submission gap** is calculated as the time from the date of submission at the first regulatory agency (out of EMA, FDA, PMDA, Health Canada, Swissmedic and TGA) to the date of regulatory submission to the target agency. **Approval time** is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. **Rollout time** is calculated from the date of submission at the first regulatory agency to the date of regulatory approval at the target agency.*
**The timelines for other NASs were obtained from industry via the CIRS Growth and Emerging Markets Programme.*

- Median submission gap reduced by 262 days.
- Median approval time reduced by 5 days.

Source: Centre for Innovation in Regulatory Science (2024) R&D Briefing 97: Access Consortium and Project Orbis New Active Substance Approvals Across Eight National Regulatory Authorities. A Five-Year Comparative Study. Centre for Innovation in Regulatory Science. London, UK.

Project ACCESS Achievements

Increase in number of products made available in Canada to patients via ACCESS

- 30 new active substances and 7 generic medicines approved through work-sharing

Reduced effort and duplication for both regulators and industry

- 4 medicines were approved through a 5-way application mechanism

Decrease in average time to market for products assessed under ACCESS

- Median rollout time 169 shorter overall compared to non-ACCESS NAS submissions.

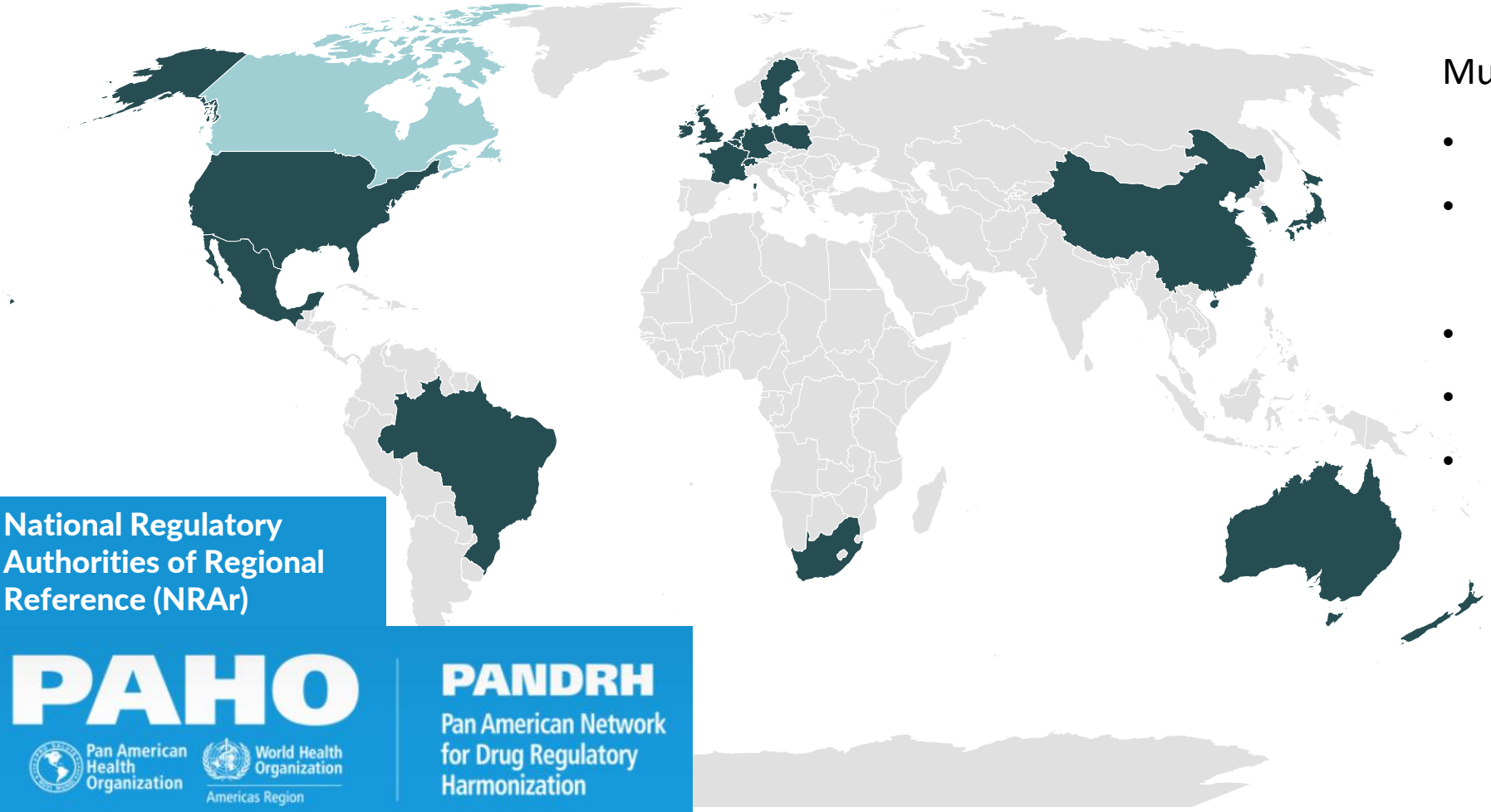
Increase in applications to ACCESS at same time or soon after submissions to other major regulators

- Median submission gap of 68 days for ACCESS NAS application

International collaboration model

- Key take-aways of successful regulatory collaborations
  - Dare to pilot innovative approaches
  - Provide ways for people to interact and exchange ideas in real time
  - Use and encourage flexibility to streamline processes
  - Leverage human resources to develop strong and clear procedures
  - Foster convergence and predictability by encouraging direct 360° communication

Confidentiality arrangements by country and multilateral organization



Multilateral Organizations:

- European Union
- Food and Agriculture Organization of the United Nations
- Medical Device Single Audit Program
- Pan American Health Organization
- World Health Organization

National Regulatory Authorities of Regional Reference (NRAr)

PAHO
Pan American Health Organization
World Health Organization
Americas Region

PANDRH
Pan American Network for Drug Regulatory Harmonization

FEEDBACK and RESOURCES

Health Canada welcomes any questions or feedback in regards to industry experience with ACCESS and ORBIS to:

Office of Regulatory Intelligence and Risk Management at collaboration@hc-sc.gc.ca

ACCESS Consortium

www.canada.ca/en/health-canada/services/drugs-health-products/international-activities/access-consortium.html

Project ORBIS

www.canada.ca/en/health-canada/services/drugs-health-products/international-activities/project-orbis.html