ACCESS Worksharing Operational Insights and Process Optimization

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CASSS Presentation

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Session Objectives

- Brief overview of ACCESS Consortium
- Specific Vaccine Case Study
- General Sanofi ACCESS Experience

ACCESS

2007
Year Founded

5
Member Countries

150M+
People Covered

≥2
Min. Countries

~300
Calendar Review Days

1
Shared LoQ

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Eligibility

Submission Rules

- Simultaneous submission to ≥2 ACCESS agencies within a 2-week window.
- Same assessment pathway (standard or priority) across all agencies.
- Expression of Interest (EOI) required ≥3 months before filing — 6 months notice for priority review.

Eligible

- New Active Substance (NAS)
- New Chemical Entity (NCE)
- New Biological Entity (NBE)
- New indications

Not Eligible

- Provisional/conditional approvals
- Variations (except new indications)

Data Alignment

- Same Modules 2–5 data set required across all participating agencies

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Access Process and Milestones

Standard pathway only.
Priority pathway is individualized with rolling questions instead of a consolidated List of Questions

1. Expression of Interest (EOI)

- Expression of Interest (3-6 months before)

2. Pre-Submission
3-6 months

- Expression of Interest (under review)
- Technical pre-submission meeting or email
- Logistic coordination (2 months before)

3. Submission & Assessment
Day 0-250

- Simultaneous submission
- Screening acceptance (30-45 days)
- Assessment & peer review (120 days) → List of Questions issued
- Response (30/60 days)
- Second round if required (15 days)

4. National Phase
Day 250-300

- End of work-sharing
- Labelling review

5. Regulatory Decision
Day 300

Near simultaneous decision

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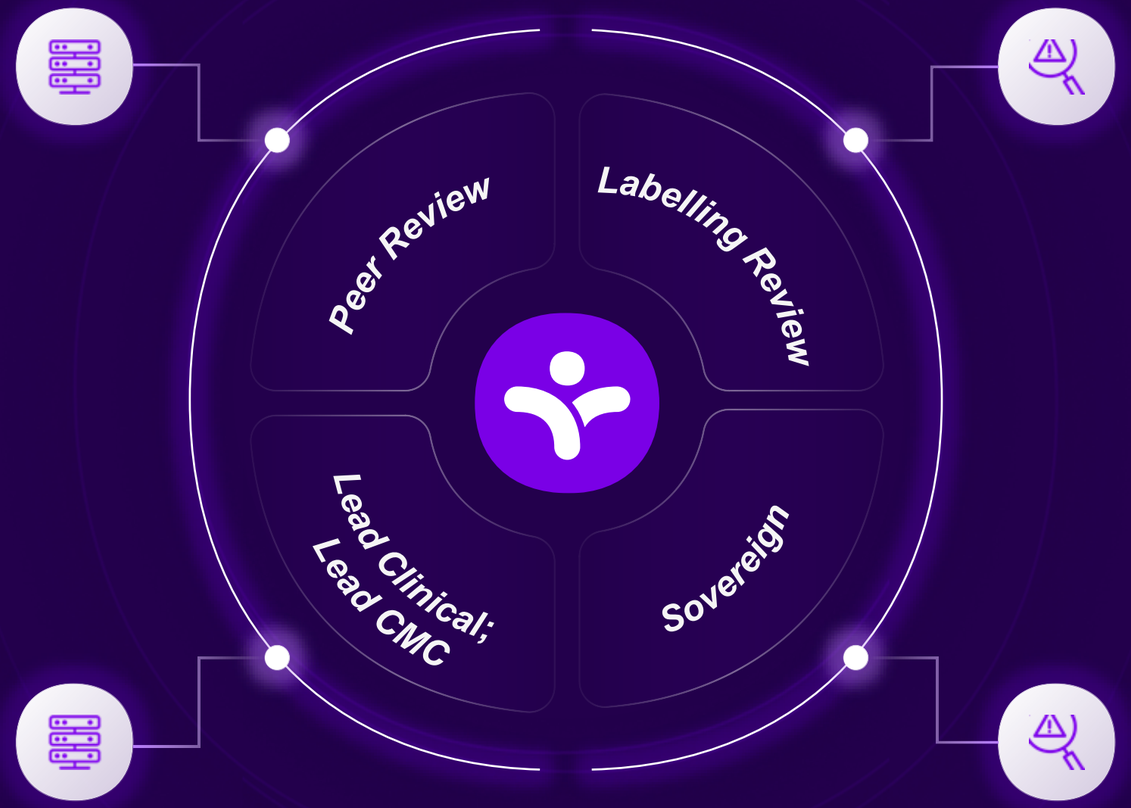
Work-Sharing Process

2. Peers

Other non-lead HA may conduct “light” peer review



3. Each Agency

Country-specific admin & labelling review — always independent

1. Lead

ACCESS HA decide on clinical lead HA and CMC lead HA (if required).

4. Final Decision

Each agency retains full sovereign regulatory authority

How Sanofi Decides to Pursue ACCESS

01

Strategic

New Molecular Entity (NME) or ext. of indication? New Active Substance (NAS) eligibility? Multi-country opportunity?

02

Regulatory

Clinical data fit? Comparator alignment? Hybrid filing viable?

03

Country Evaluation

AU, CA, SG, CH, UK fit? Country barriers? Authority engagement?

04

Business

Commercial buy-in? Launch readiness? Competitive positioning?

05

Timeline

Dossier date confirmed? 3–4 months lead time? EOI target set?

Business Alignment

- Commercial buy-in confirmed in each country
- Launch readiness & market access aligned
- Competitive positioning assessed per market
- Affiliate perspective & local needs captured
- Resource availability confirmed across teams

GO / NO-GO Decision

- Cross-functional sign-off: global reg., affiliate reg., business
- 'One voice' strategy for Wave 1 filing confirmed
- Management approval obtained
- Decision made with buffer before dossier date
- Contingency plan for potential barriers in place

ACCESS Journey: Vaccine SNDS New Indication

- Two years prior to submission – consideration of ACCESS pathway for vaccine new indication across all 5 countries.
- One year before submission, internal ACCESS Strategy Meeting initiated
- Six months before submission - EOI submitted (all 4 countries synchronized)
- Q1 2025 – Health Canada confirms participation, provides HC evaluation plan. All 4 countries submit same dossier.
- 6 months after submission LoQ 1 received from Singapore (clinical lead)
- 9 months after submission, national phase begins for Canada – labelling review starts
- 12 months after submission –approval received across all 4 countries within 6 week span

Sanofi ACCESS Experiences

TOTAL: 13 (11 with Health Canada) – 2 currently under review
NDS = 3
New indications = 10
New indication with CMC = 1
Rejected by HC for ACCESS priority = 1
Rejected by HC for ACCESS pathway = 1

Advantages	*Considerations*
• Health authorities commit to meeting 250-day review timeline • Consolidated list of questions (LOQ), Simplified coordination for global teams • Standard 30/60-day response window • Less “rolling questions”	AU clinical lead: external advisory committee may delay decision by up to 2-months • Health Canada requires a 2-week longer screening period than other countries and submissions must be on same day • Lead country's negative decision may affect others • Significant affiliate planning required

Thank You

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