Australian Government
Department of Health
Therapeutic Goods Administration

Work-sharing, Reliance, and Other Novel Approaches to Accelerating Review, Approvals, and Access

An Australian perspective

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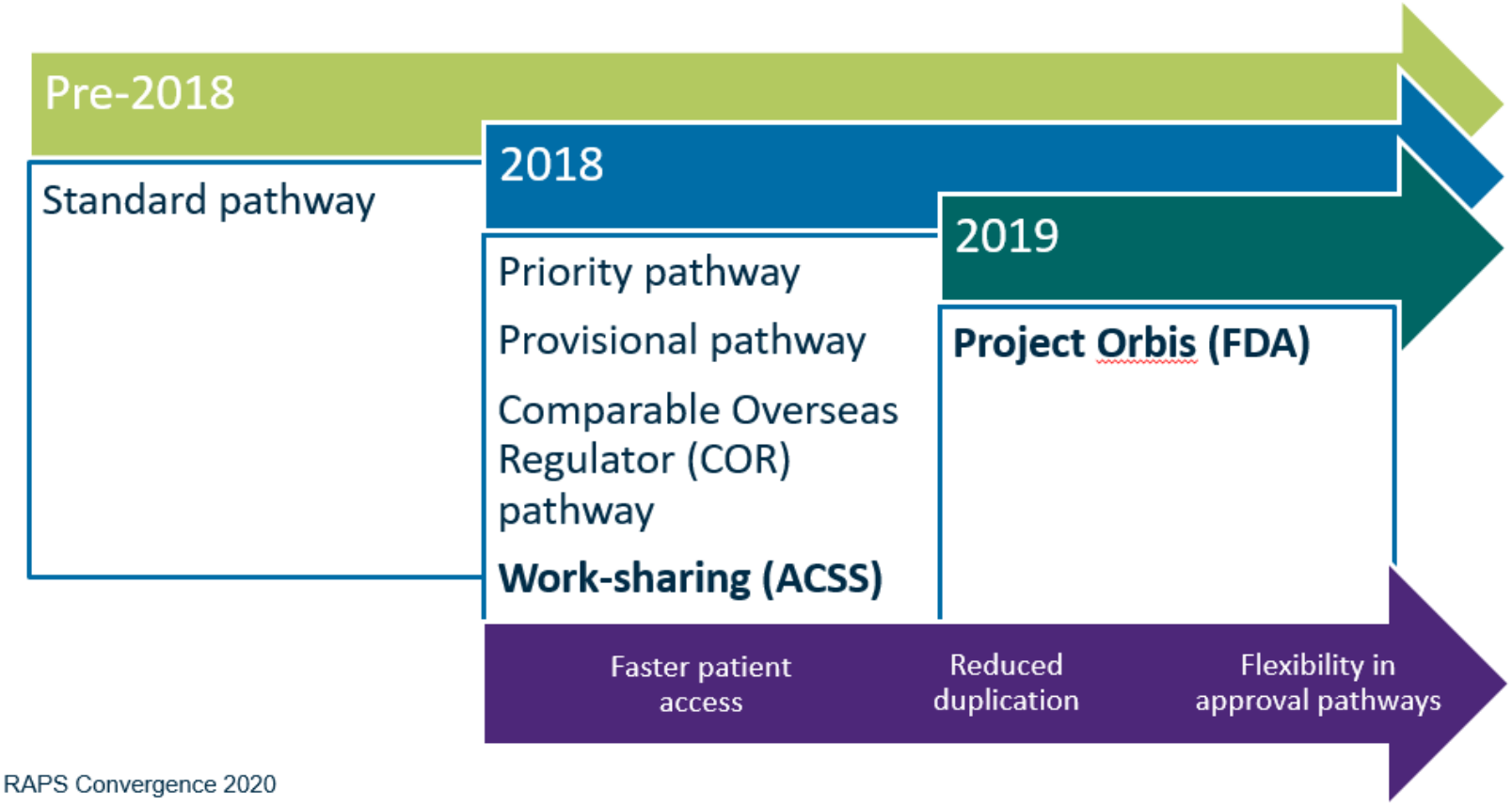
TGA Health Safety Regulation

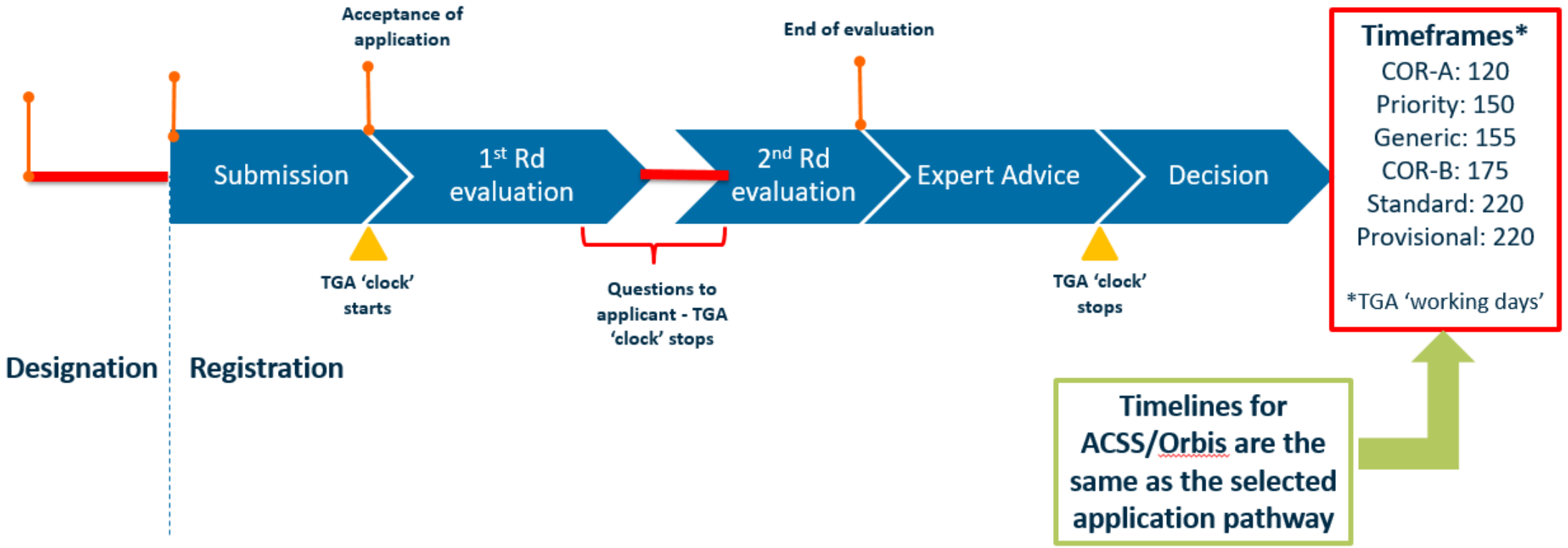
Overview

- Overview of TGA's reliance pathways and principles
- Use of comparable overseas regulator (COR) reports to abridge assessments
- Work-sharing via the Australia-Canada-Singapore-Switzerland Consortium (ACSS)
- Comparison – which reliance pathway is right for you?

TGA registration pathways



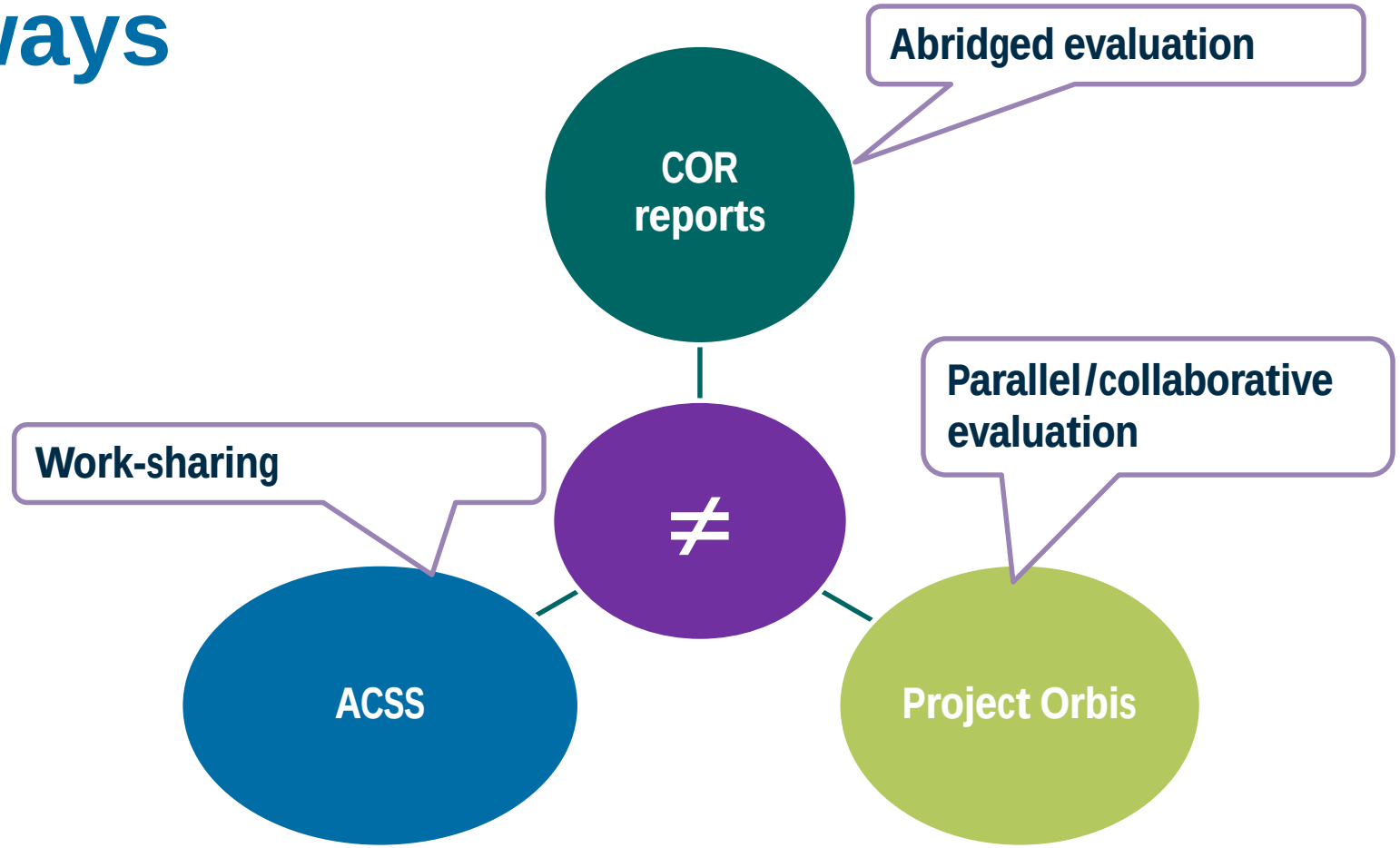
Snapshot: Designations and pathways



TGA reliance pathways

Key principles:

- TGA sovereignty over decision making
- Reliance **does not** represent a less robust form of regulation
- Regulators we work with have similar values and approaches to critical decision-making
- Reliance provides flexibility to TGA/applicants and can be tailored to the needs of the regulatory system



Industry's support and adherence to these principles is vital to the success of these pathways

COR report-based process

- The TGA uses assessments from Comparable Overseas Regulators (CORs)

- Key features:
  - a list of countries and jurisdictions from whom TGA will accept reports (CORs)
  - transparent criteria and guidance for identifying CORs
  - a process for using overseas reports

- The TGA will only evaluate data generated specifically for the Australian context

Use of comparable overseas regulator reports

COR-A

- Approved overseas < 1 year
- Identical medicine and supply chain
- Identical dossier (except Module 1)
- Approval < 120 working days (legislated)

COR-B

- No approval timing restrictions
- Identical medicine and supply chain
- Additional data allowed (e.g. post-approval variations, clinical data updates)
- Approval < 175 working days (legislated)

Completed submissions*
COR-A: 5
COR-B: 11

***Since 2018**

COR report-based process

- TGA identifies CORs using the 'Criteria for identifying CORs'

Pre-submission

- Applicants use 'Criteria for acceptance of COR reports' to determine if a particular report is suitable

Submission

- Submission of **un-redacted COR report** and full dossier
- TGA confirms application is eligible for COR report-based process during screening

Evaluation

- TGA evaluation based on COR report(s) **AND** evaluation of data generated specifically for the Australian context

Use of comparable overseas regulator reports

Industry

- Faster market access for new products
- Decreased workload through reduced set of RFI
- Predictability through reduced approval timeframes
- Transparency around likely acceptance of reports

TGA

- Improved efficiency with potential to reduce regulatory effort
- Best of both worlds – sovereign decisions and potential for greater international harmonisation
- Share expertise across regulators

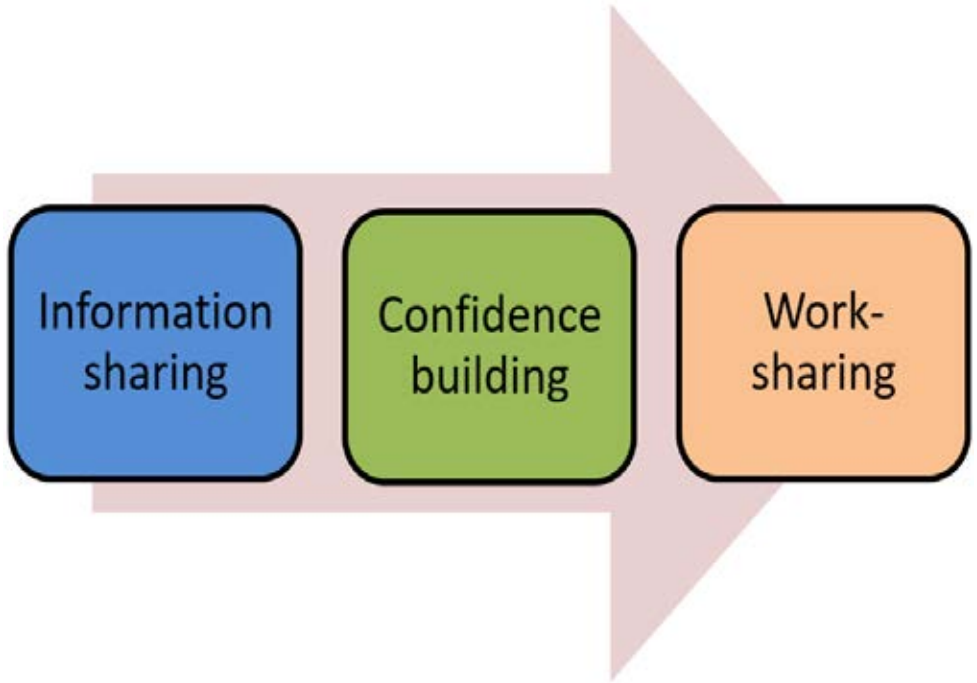
Benefits for all

ACSS New Active Substance (NAS) Work Sharing Initiative

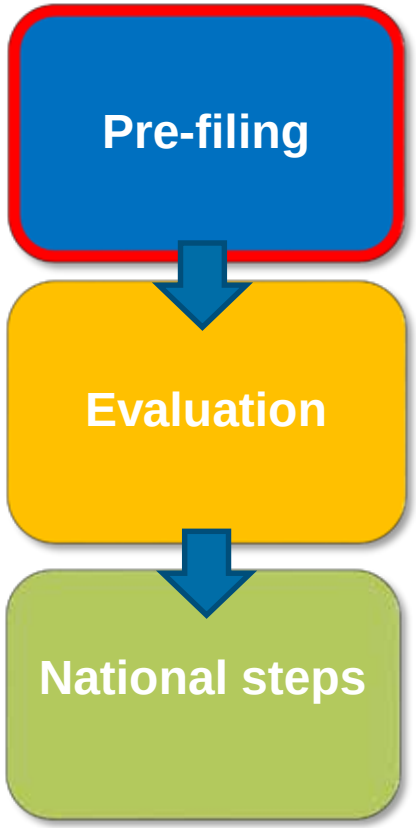
ACSS CONSORTIUM
AUSTRALIA
CANADA
SINGAPORE
SWITZERLAND

- The Australia-Canada-Singapore-Switzerland (ACSS) Consortium is a group of like-minded, medium sized regulatory authorities.
- ACSS partners have been sharing information since 2007
  - Network of bilateral confidentiality agreements and Memoranda of Understanding
  - gaining comfort and confidence in each others processes and evaluation reports
- Work-sharing commenced in 2018

Journey to international work-sharing.....



ACSS work-sharing process



- Applicant Expression of Interest (EOI) *at least **3 months*** before the intended filing date.
- Agreement of partner regulators to participate
- Participating regulators negotiate a division of labour and joint-review timeline, e.g.:
  - Mod 3 (± BE)
  - Mod 4 (+ impurities consult)
  - Mod 5 (± popPK, clinical pharmacology)
- Evaluation plan tailored to each submission through negotiation

ACSS work-sharing process

- Agencies evaluate their assigned module(s) and any country specific aspects:
  - Mod 1 (labels, GMP, RMP)
  - Mod 3 (TGOs, stability, container)
  - Mod 4 (pregnancy category)
  - Wording of indications
- Consolidated technical questions
- Inter-agency interactions throughout the review (evaluator t/c)

ACSS work-sharing process

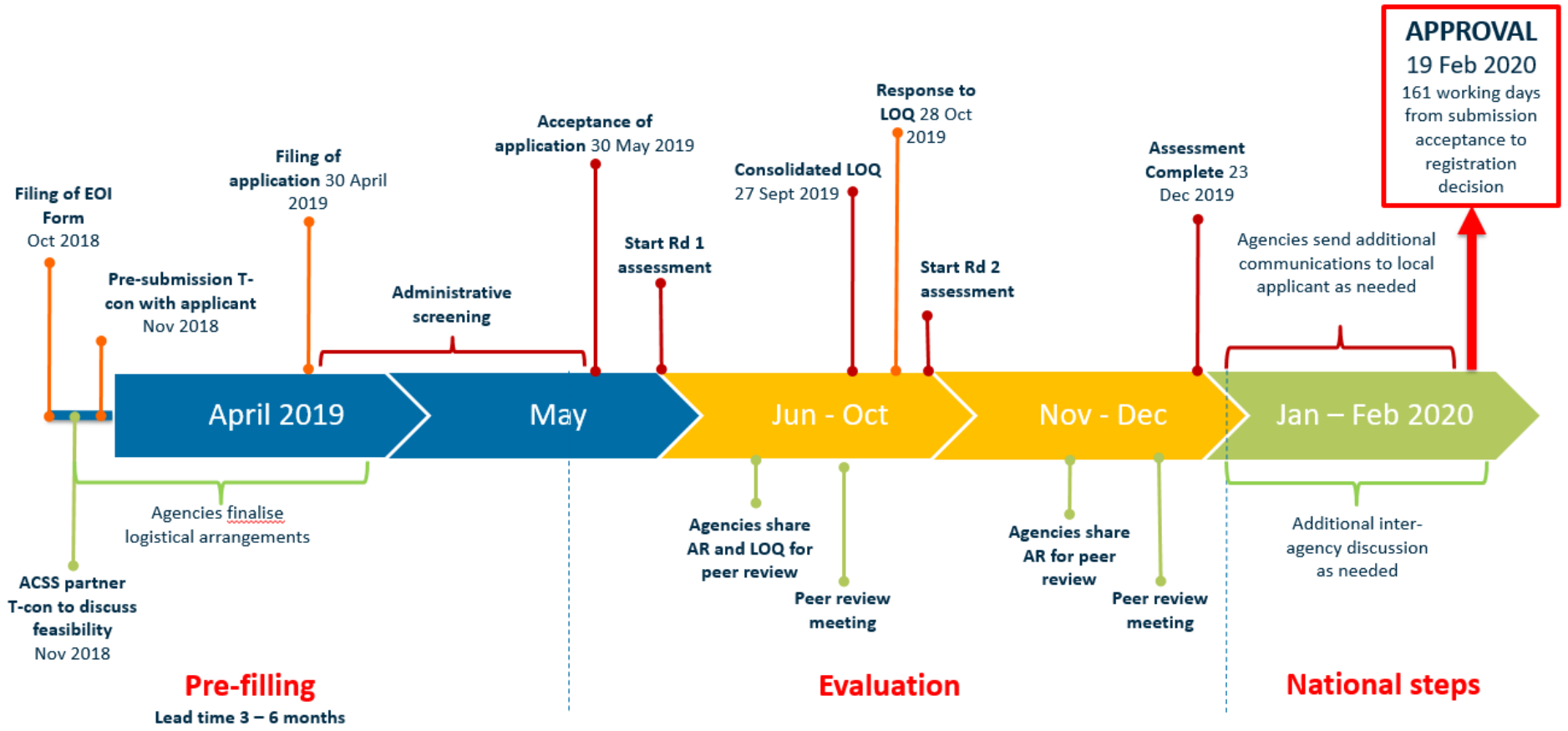
Pre-filing

Evaluation

National steps

- Work-sharing concludes at the end of the evaluation
- **National steps include:**
  - expert advice
  - wording of indications
  - Finalisation of product label
  - subsidy/reimbursement
- Independent decision-making by each jurisdiction
- **Near** simultaneous decisions

Case study: Baloxavir



ACSS – Completed submissions

Submission	Indication	Module 3 Quality	Module 4 Non-clinical	Module 5 Clinical	Approval
ERLEADA (apalutamide)	Prostate cancer			 	July 2018
VERZENIO (abemaciclib)	Breast cancer				April 2019
ZEJULA (niraparib)	Ovarian cancer				June 2019
XOFLUZA (baloxavir marboxil)	Anti-viral (influenza)				Feb 2020
NUBEQA (darolutamide)	Prostate cancer				Feb 2020
VYNDAQEL (tafamidis)	Cardiomyopathy			 	March 2020
SARCLISA (isatuximab)	Multiple myeloma				Apr 2020

ACSS benefits

Benefits

- Reduced duplication
- Sharing expertise
- Collaborative approach to decision making leading to more robust decisions
- Better access to medicines for the Australian community

Challenges

- Resource implications for both the coordination and evaluation aspects
- Slightly shorter evaluation timeframes to accommodate peer review
- Different processes – decision makers, transparency
- Different national requirements, TGOs & different sovereign decisions

ACSS work-sharing - tips and tricks

- **Advance Notice**: Early interactions with regulators to assess whether work-sharing is a feasible option
- **Coordinated Filing**: prepare for submission to each regulator within 2 week window
- **Identical dossiers** across jurisdictions (noting country-specific aspects) – note differences in EOI
- Possibility of **near simultaneous access** to ACSS markets **BUT** reimbursement not part of work-sharing

Which TGA reliance pathway is right for you?

COR report-based

- Submitting to TGA (only)
- Suitable for **all** therapeutic areas
- Applicants **must** provide reports to TGA that meet legislated criteria
- TGA conducts **abridged assessment** based on COR report(s) in lieu of *de novo* evaluation
- Timeframes are reduced

Work-sharing

- Submitting to 2 or more of Australia-Canada-Singapore-Switzerland (ACSS) Consortium
- Suitable for **all** therapeutic areas
- Applicant(s) submit Expression of Interest
- Regulators **divide review of safety quality, efficacy modules**
- Standard timeframes apply

Project Orbis

- Submitting to US FDA **and** TGA (& others)
- Oncology drugs **only**
- Suitable applications identified by FDA
- Regulators conduct **parallel, collaborative evaluation** and share information
- Timeframes **may** be reduced

Further information

COR report-based process

- Comparable overseas regulators (CORs) for prescription medicines

ACSS work-sharing

- ACSS - NAS work sharing initiative
- Guidelines for Industry
- Frequently asked Q&A
- ACSS NAS work-sharing initiative Expression of Interest (EOI) form

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