From Foundations to Frontiers:
The Evolving Landscape of Biologics Regulation in Canada

CAPRA ACPR | Biologics & Biosimilars Symposium – March 28, 2025

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1. Foundations & Frontiers: the Monoclonal Antibody Example
2. Canadian RA Professional – High Level Industry Perspective
3. Evolving Regulatory Landscape for Biologics in Canada
4. Future Directions & Moving the Needle
5. Role of the RA Professional working with Biologics

Antitoxins, Serum Products
19-20th century

Antibody Humanization
1985 - 1986

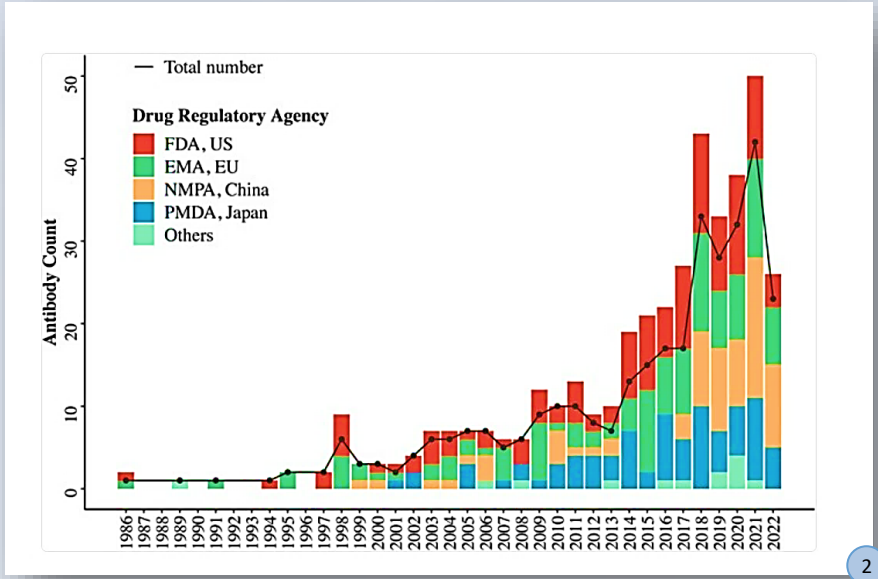
First humanized mAb
Trastuzumab
HERCEPTIN
1998

>110 billion USD global sales
2021

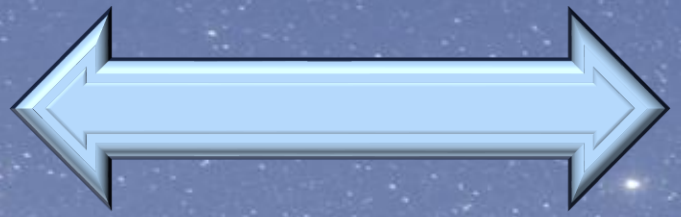
>100 distinct therapeutic mAbs
2021

Hybridoma Technique
1975

First mAb
Orthoclone OKT3
Humanization
1986



Monoclonal antibodies are “well-characterized biotherapeutics” and have become standard of care for the treatment of many serious or life-threatening diseases

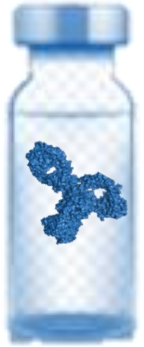


Foundations

- “Well-characterized” biologics
- Medically significant products
- Available Pathways & Frameworks

Frontiers

- Novel, complex, and distinct biologics
- Medically significant products
- Challenge conventional Pathways & Frameworks

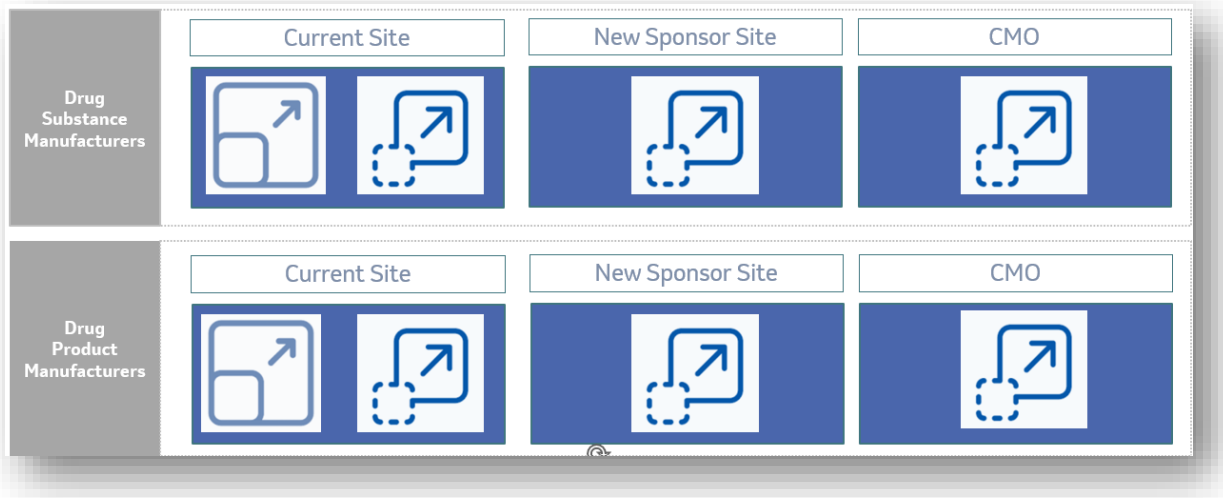


Canadian RA Professional – High Level Industry Perspective

1) Agile & Flexible Regulatory Approval

- Medicine with Safety, Efficacy, Quality
- Scientific, data driven, & rationale-based decisions
- High standards for regulatory review
- Rapid access for Canadian patients for treatment of unmet medical needs

2) Maintain Supply, with Streamlined Post-Approval Requirements



Large Number of Post Approval Changes

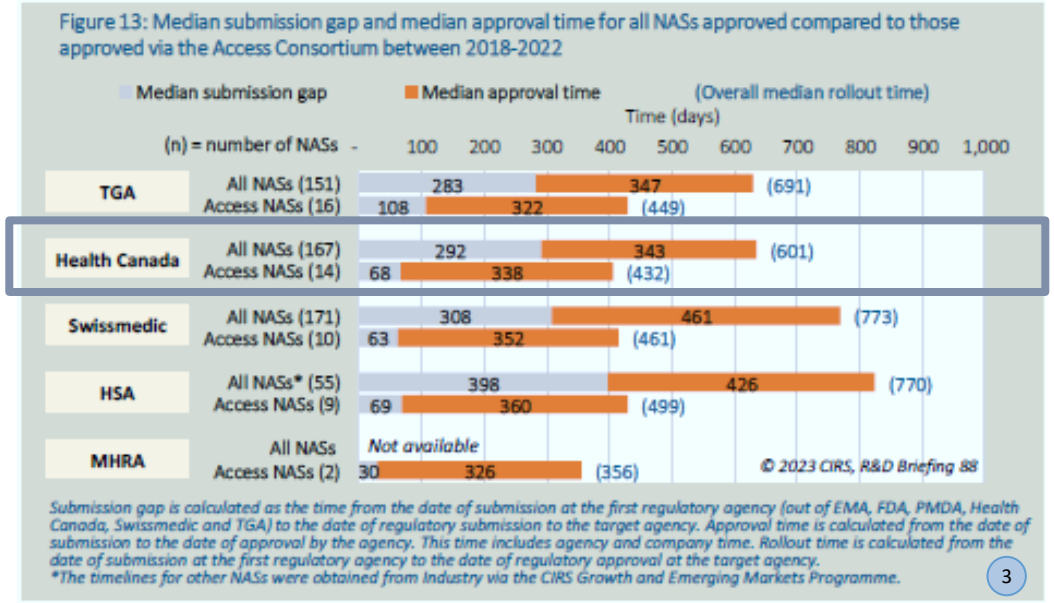
Evolving Regulatory Landscape in Canada

1) Regulatory Innovation For Health Products

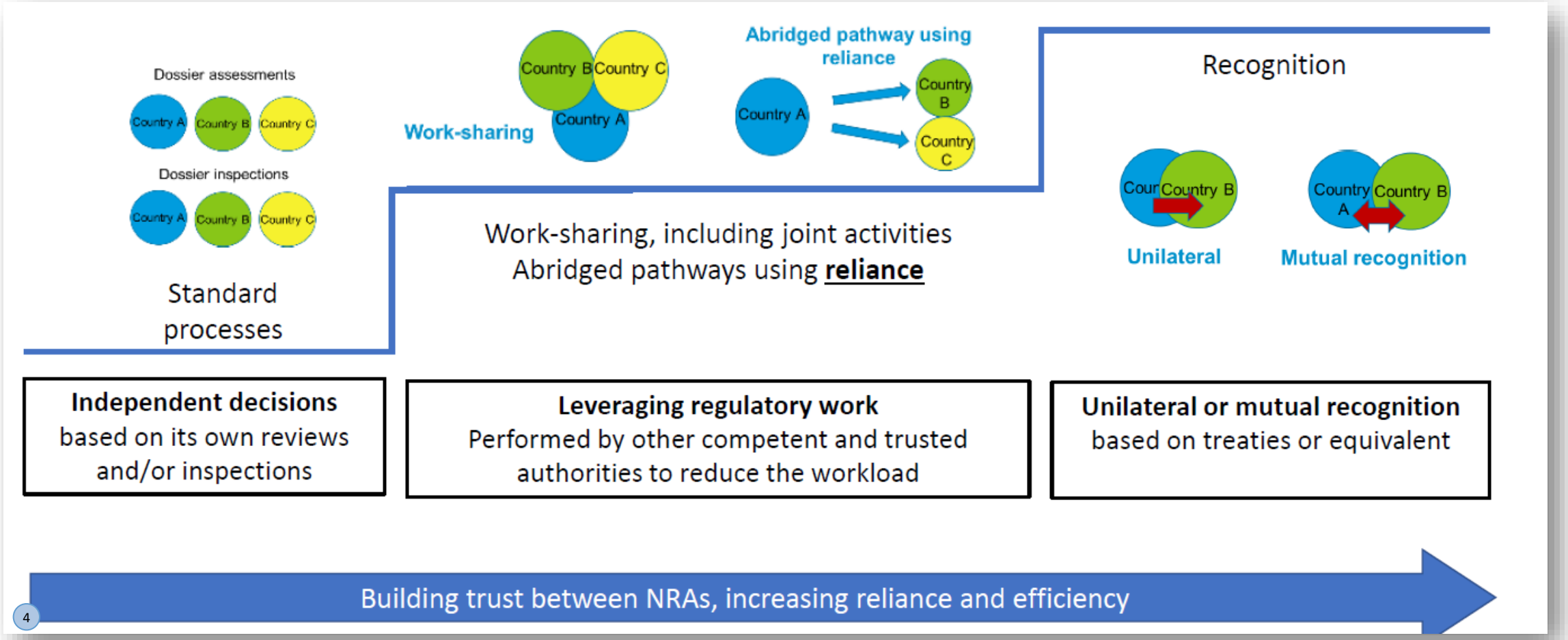
- Agile Licensing
- Precision Regulations
- Modernizing DEL Framework
- Drug Shortages Regulations
- NSNR (O)

2) International Harmonization & Collaboration Initiatives

- ICH
- ORBIS
- ACCESS
- ICMRA
- PIC/S



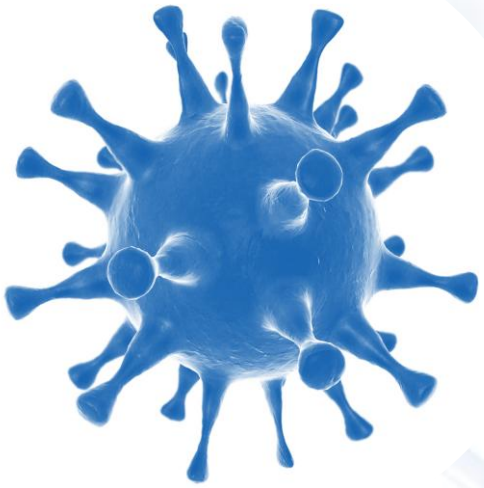
Moving the Needle & Advocacy



Moving the Needle-Canadian RA Perspective

- Maximize work sharing and mutual recognition
- Maximize harmonization and convergence
- Minimize divergence and duplication
- Leverage technology moving towards electronic submission platform

Evolving Regulatory Landscape in Canada



Advanced Therapeutic Products

SCHEDULE G
(Sections 2 and 21.91)

Item	Description

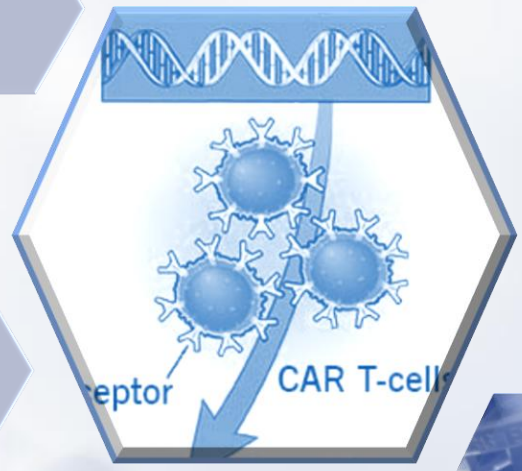
Agile Licensing: Public Health Emergency Drug

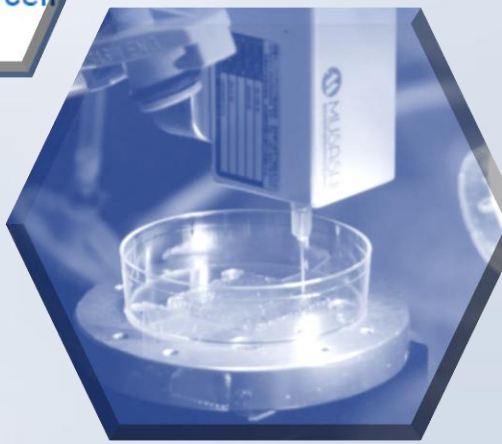
List of conditions that threaten public health

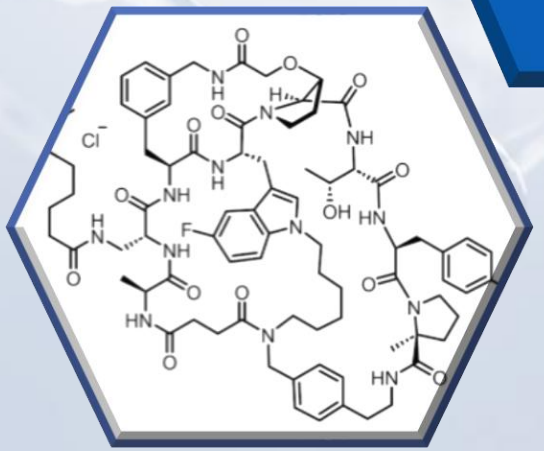
Name of condition	Clinical description
COVID-19	Coronavirus disease 2019

Clinical Trials Modernization

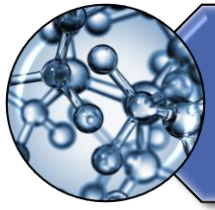
Future Directions: Where are we going?



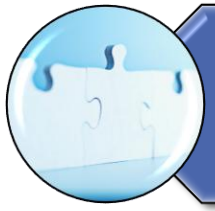




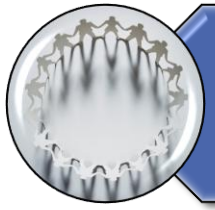
RA Professional in the Biopharmaceutical Industry plays an Important Role



Knowledge of the technology, product, and mechanism of action



Understanding regulatory landscape, frameworks, and needs of regulators



Guide team of scientific and medical experts for proposals to regulators based on requirements, data, and rationale

Be forward thinking

Thank You!

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For further information:

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