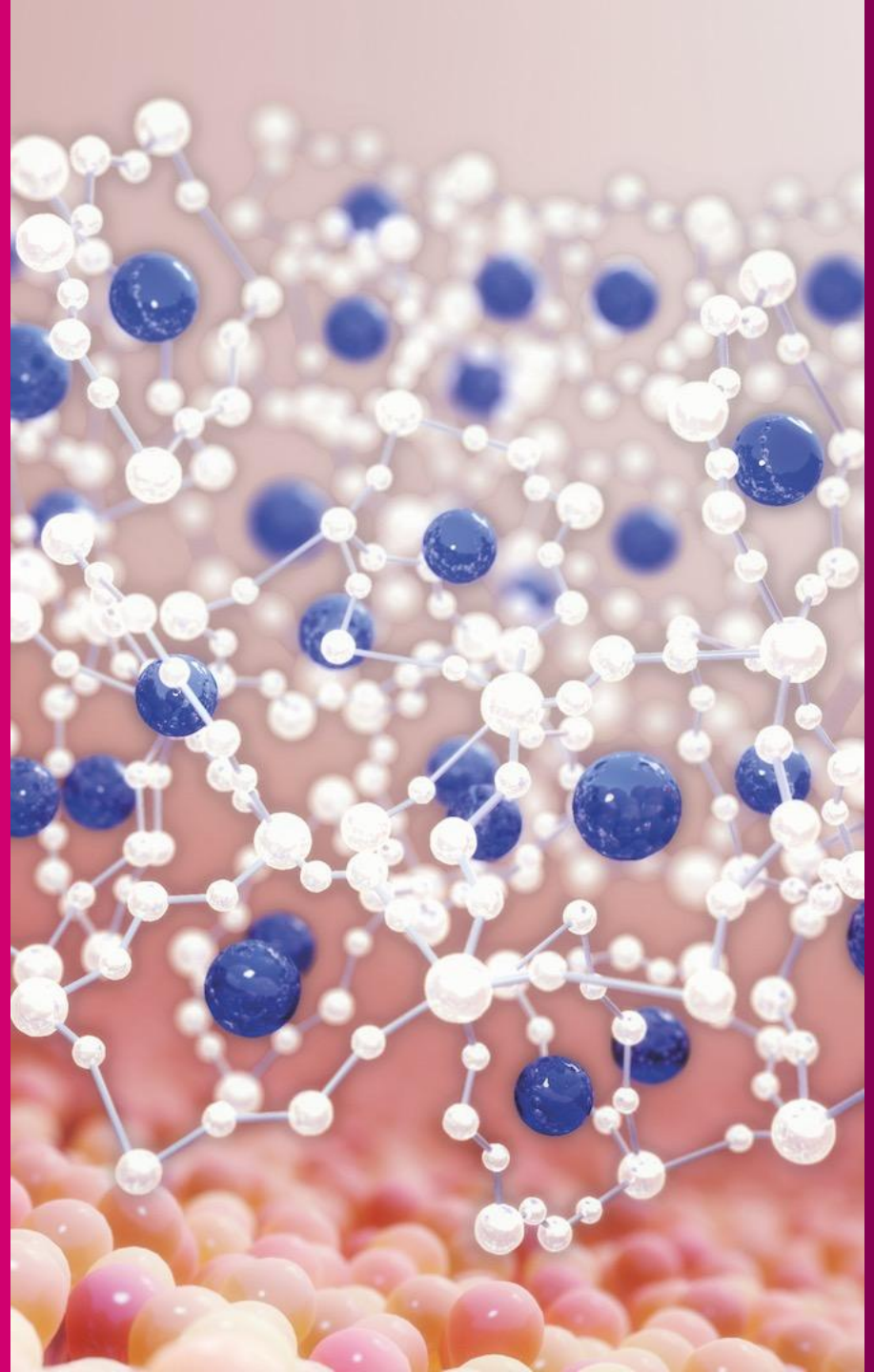


Advancing Global Submissions Through A “One Dossier” Operating Model

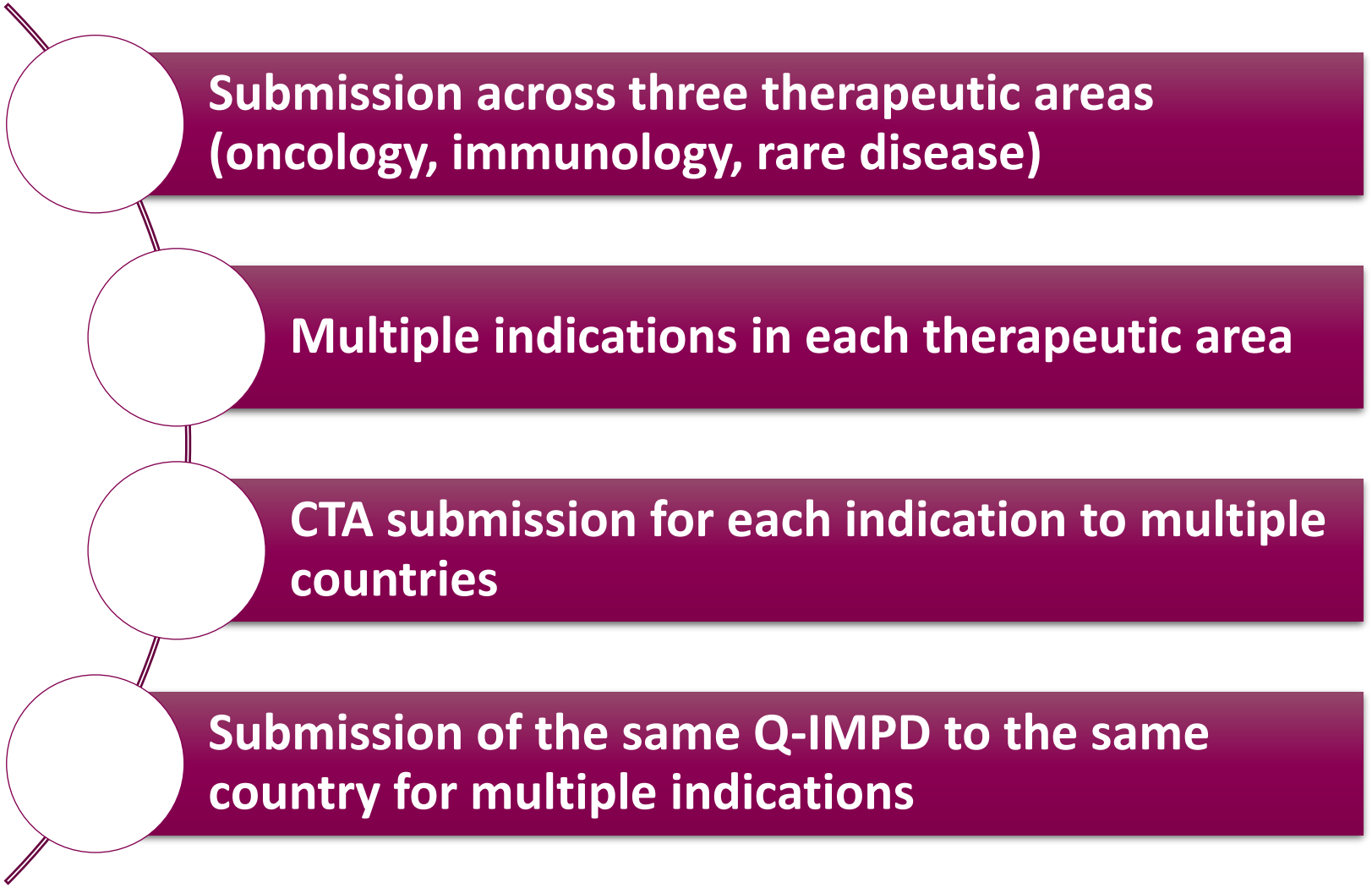
Jen Pappas, MS, MHS | AstraZeneca | CASSS CGTP | June 2026

The Regulatory Challenge

Autologous, genetically modified, dual target T cell product with multiple clinical trials in different markets.

Harmonization	"One dossier" operating model for Q-IMPD: ° Single, globally aligned submission ° Structured, reusable content
Efficiency	Faster review times Streamlined communication with regulators Shorter time to market for innovative therapies
Consistency	Improved quality and consistency of regulatory data Coherency across regions

Ex-U.S. Logistics



Points to Consider

1	2	3	4	5	6
Cross-Referencing	**Order of Submission**	**Component Versioning**	**Tracking**	**Change Control**	**One Dossier**
Cross-referencing one CTA when submitting multiple indications to the same Health Authority	Overall strategy for decision of which indication to lead submissions to a given Health Authority or region	Proactively prepare internal structure to accommodate regional modular versioning	Proactively prepare internal structure to: 1) track submissions 2) align responses 3) centralize attachments 4) Plan future submissions	Consistent, active communication with Quality, Supply Chain, Manufacturing	Proactive strategy to: 1) align ex-U.S. Q-IMPD with IND Module 3 2) align roll-out of versions across indications and countries

Successes/Work-In Progress

Successes

Logistics Framework

- Proactive establishment of logistics operating framework:
  - Responding to RFIs
  - Program management (timelines, meetings)
- Clear lines of communication, responsibility

Timeline Adherence

- Allowed for timely clinical trial launches
- Built trust cross-TA
- Required constant, flexible communication up, down and within/across each TA

Cross-Therapeutic Area (TA) Coordination

- One small, cross-TA core group for coordination
- Clear lines of communication, responsibility

Work-In Progress

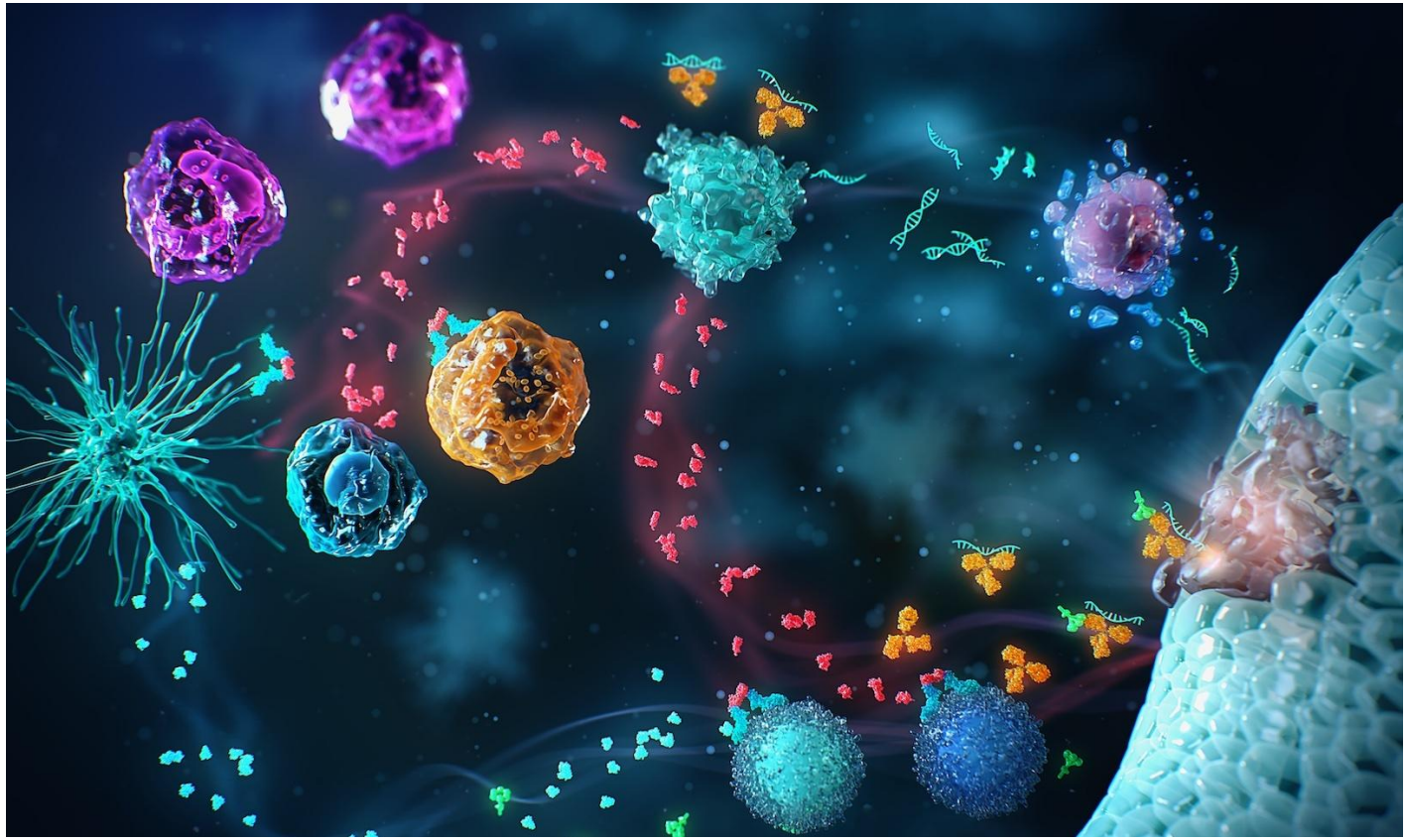
Multiple Priorities

- Unexpected type and number of questions in RFIs
- Concurrent Q-IMPD substantial amendments with significant RFIs from ex-U.S. Health Authorities

Variable Health Authority Review Timelines

- Required continuing flexibility for planning Q-IMPD amendments/country
- Challenges with roll-out of CMC changes across regions

Thank You!



Acknowledgements

- Rashi Srivastava
- Alex Beumer Sassi
- Jessica Eisenstatt
- Yoonji Preville
- Mohammed Hafidh
- Aileen La
- Rashmi Dalvi
- Chenghong Wei
- Leakhena Som
- Maria Fernandez
- Madhav Thakallapally
- Kyle Brownson
- Bao Nguyen
- Reeshelle Sookram
- Emily Lowe
- Colin Flinders
- John Tran