VECTOR LIFE SCIENCES

Coffee with an eCTD Expert
- Related Sequences -

Free Webinar

Take part in crucial conversations on Demystifying Related Sequences in eCTD Submissions.

27 August 2025

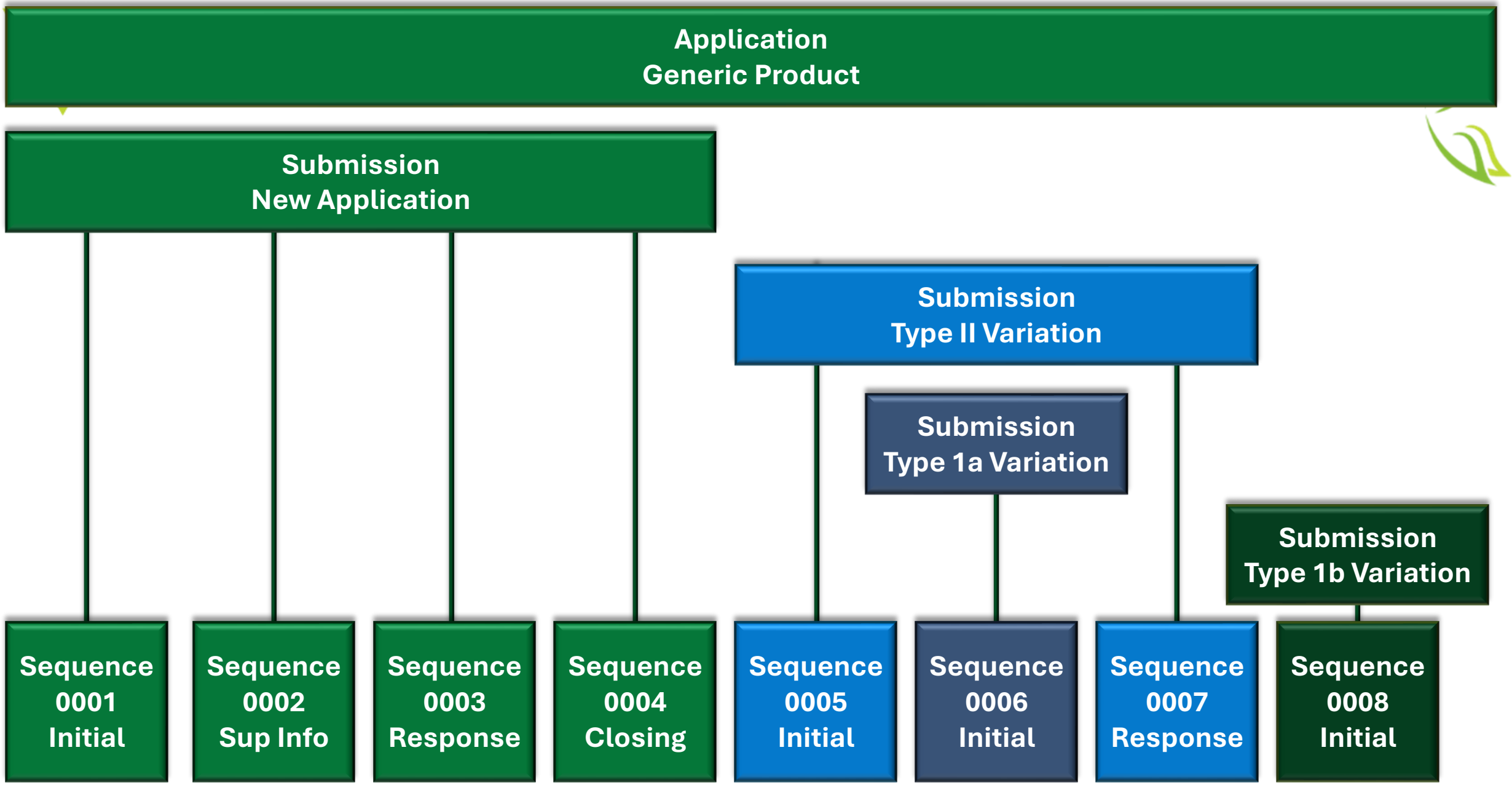
13h00 - 14h00 (SAST)

Presenter: Dr. Madelein Terblanche

The Related Sequence

- What is a Regulatory Activity?
- When do I relate a sequence?
- What if a have a response to a response?
- Where does the submission number fit in?
- Cancellations and withdrawals
- Baselines

What is a regulatory activity?


Application
Generic Product
Submission
New Application
Submission
Type II Variation
Submission
Type 1a Variation
Submission
Type 1b Variation
Sequence
0001
Initial
Sequence
0002
Sup Info
Sequence
0003
Response
Sequence
0004
Closing
Sequence
0005
Initial
Sequence
0006
Initial
Sequence
0007
Response
Sequence
0008
Initial

When do I relate a sequence?

Related Sequence No. vs. Reg. Act. Starting Sequence Mad

Sequence Number	Submission Type and Description	Regulatory Activity Starting Sequence	Related Sequence Number
0001	New Application	0001	0001
0002	Response to P&A Recommendations	0001	0001
0003	Response to 2nd P&A Recommendations	0001	0001
0004 APPROVED	Response to Clinical Recommendations	0001	0001
0005	Application for Variation C #1	0005	0005
0006	Application for Variation B	0006	0006
0007	Response to Variation C #1 P&A	0005	0005
0008	Application for Variation C #2	0005	0005
0009	2nd Response to Variation C #1 P&A	0005	0005

What if a have a response to a response?

The Related sequence is **ALWAYS**

the initial sequence of the submission

- The start of the regulatory activity

Where does the submission number fit in?

Cancellation of an **APPLICATION** **vs** Withdrawal of a **SUBMISSION**

Withdrawals

	Application Withdrawal	Submission Withdrawal
Submission Type	“Application Withdrawal”.	Type set in the Related Sequence
Sequence Type	“Initial”.	“Submission Withdrawal”.
Sequence Description	“Cancellation”.	“Withdrawal of…”
Related sequence	Itself	“Initial” Sequence of the Submission
Life Cycle	A Letter of Application should be included as “New” and explain why the eCTD Application is being withdrawn	• The Letter of Application should be the only document submitted as New • Content that was replaced by the Submission must be reset referencing the document that was previously referenced in the earlier Sequence using the Replace operation. The document should NOT be provided again. • Content that was added as New in the Submission must be removed using the Delete operation. • **DO NOT remove** any content belonging to the other Submissions using the Delete operation.
	No further content or life cycle is required.	**Submission Withdrawals and Work Grouping***

BASELINES

Initial eCTD Sequence

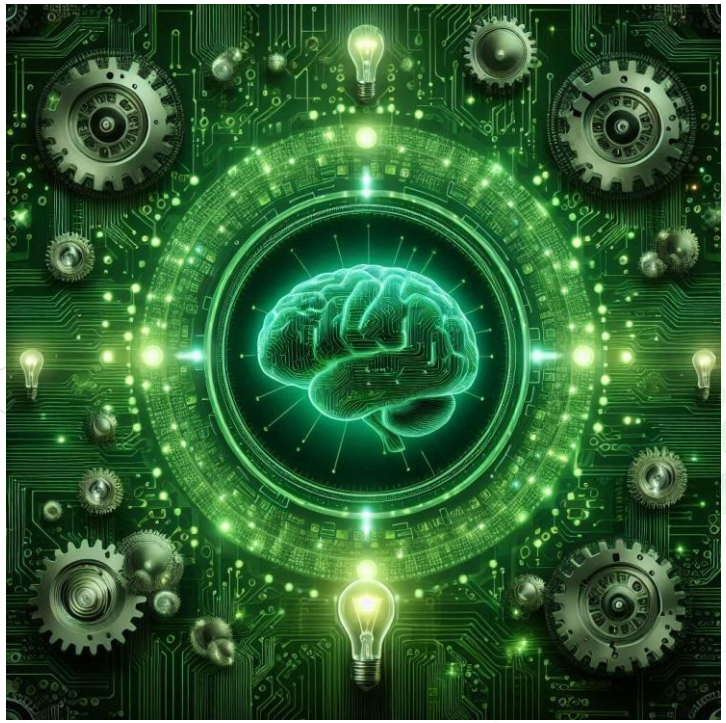
Sequence	Submission Type	Sequence Type	Related Sequence
0000	Baseline	Initial	0000
0001	Type IB - Clinical	Initial	0001
0002	Type IB - Clinical	Response	0001
0003	Type II - Proprietary Name Change	Initial	0003
0004	Type II - Safety (Clinical)	Initial	0004

Iterative Baseline

Sequence	Submission Type	Sequence Type	Related Sequence
0000	Baseline	Initial	0000
0001	Type II - Safety and Efficacy (Clinical)	Initial	0001
0002	Type IB - Quality	Initial	0002
0003	Type II - Safety and Efficacy (Clinical)	Response	0001
0004	Baseline	Supplementary Information	0000
0005	Type II - Quality	Initial	0005

Mid-Life Cycle Baselines

What now?



- 3.2.P Drug Product [redacted] [solution] [FPP Mnf-1 (API Mnf-1)]
- 3.2.P Drug Product [redacted] [solution] [FPP Mnf-2 (API Mnf-2)]
  - 3.2.P.3 Manufacture
  - 3.2.P.5 Control of Drug Product
  - 3.2.P.6 Reference Standards or Materials
  - 3.2.P.8 Stability
- 3.2.P Drug Product [redacted] [Solution] [FPP Mnf-1 (API Mnf-1)]
- 3.2.P Drug Product [redacted] [Solution] [FPP Mnf-2 (API Mnf-2)]
  - 3.2.P.1 Description and Composition of the Drug Product
  - 3.2.P.2 Pharmaceutical Development
  - 3.2.P.3 Manufacture
  - 3.2.P.4 Control of Excipients [Compendial]
  - 3.2.P.5 Control of Drug Product
  - 3.2.P.6 Reference Standards or Materials
  - 3.2.P.7 Container Closure System
  - 3.2.P.8 Stability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Q&A
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Sponsor Recognition

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Virtual, Microsoft Teams

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