Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

CTIS Webinar: Last Year of Transition

Session 2:

Experience in Transitional Trials

Member States' Perspective

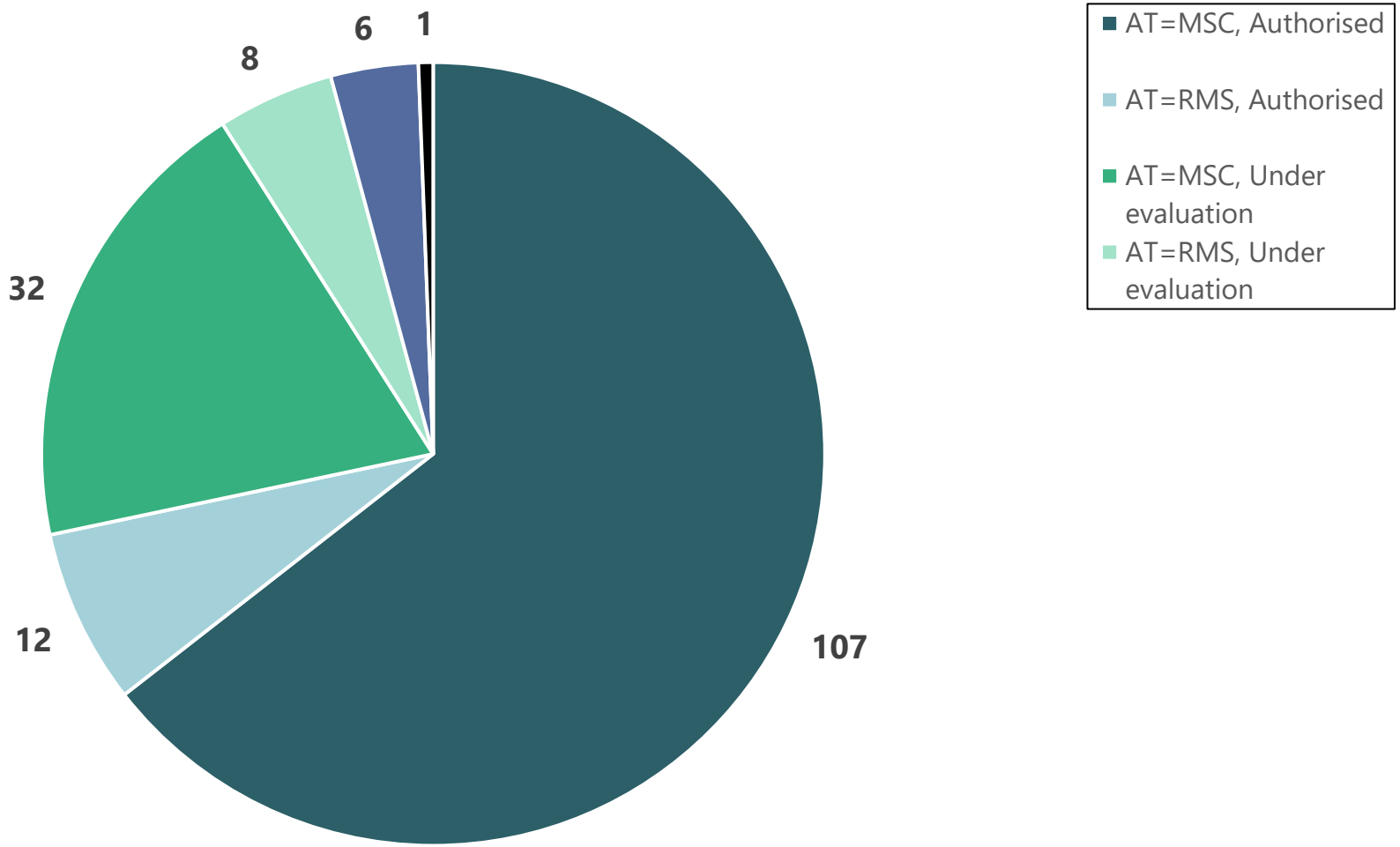
Stefan Strasser, MD

Head of Clinical Trials, Austrian Medicines and Medical Devices Agency

Transitions in Austria

Our experience so far…

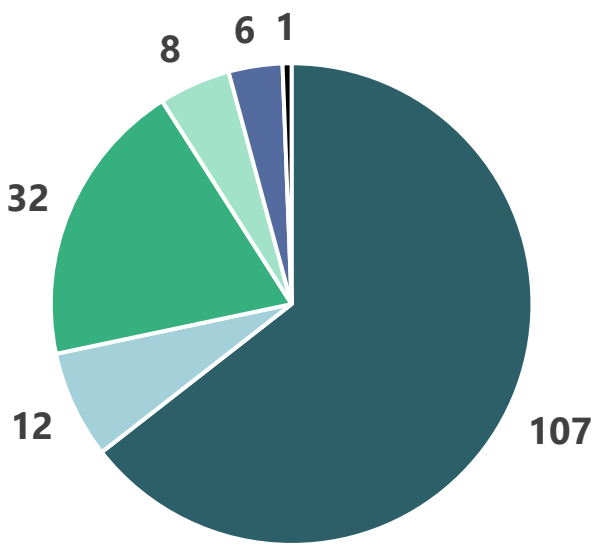
Bundesamt für Sicherheit im Gesundheitswesen
BASG

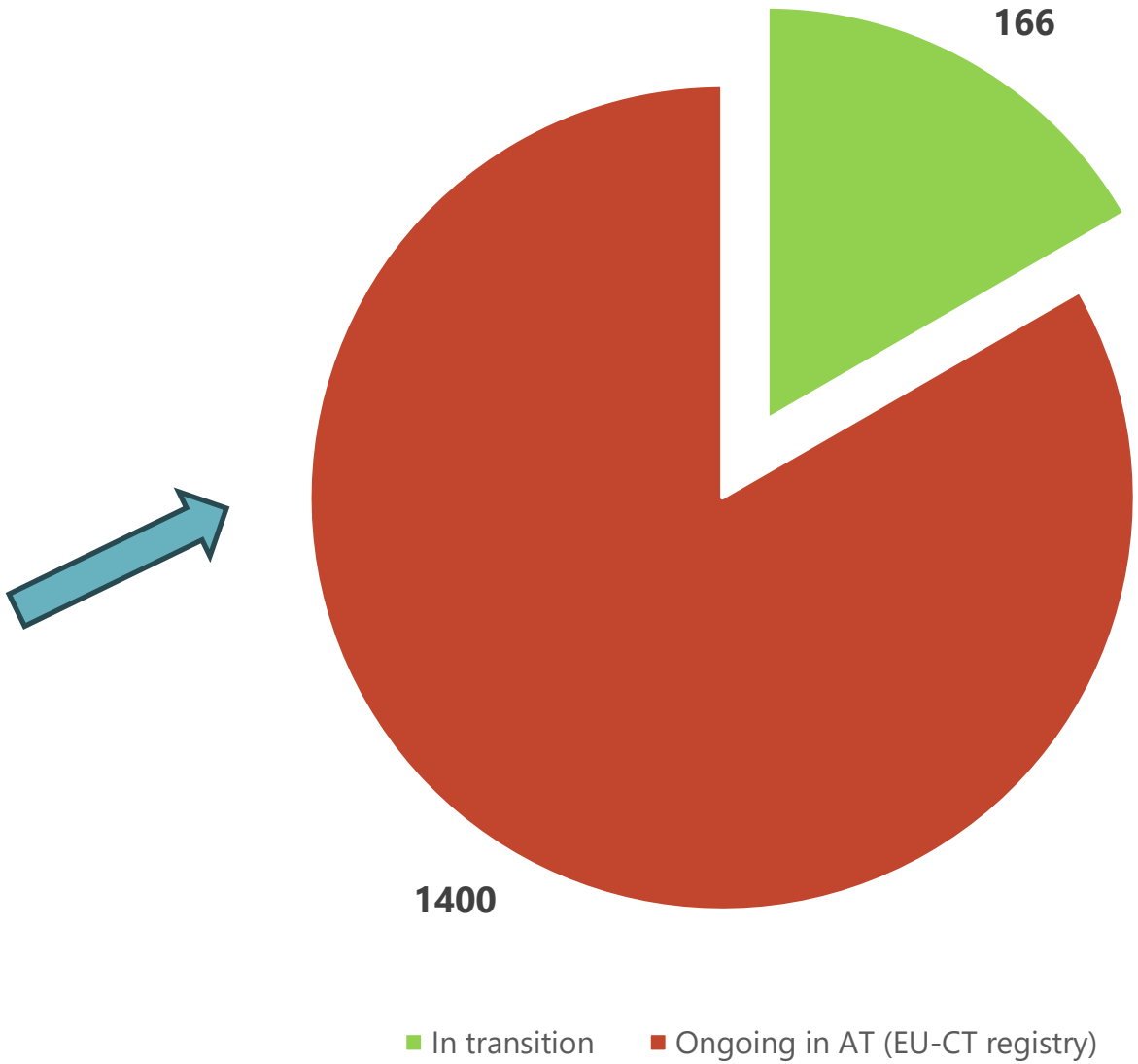


We need more from you!

There is more in front of us than behind us…

Bundesamt für Sicherheit im Gesundheitswesen
BASG





Follow the guidance!

Makes live easier for all of us…

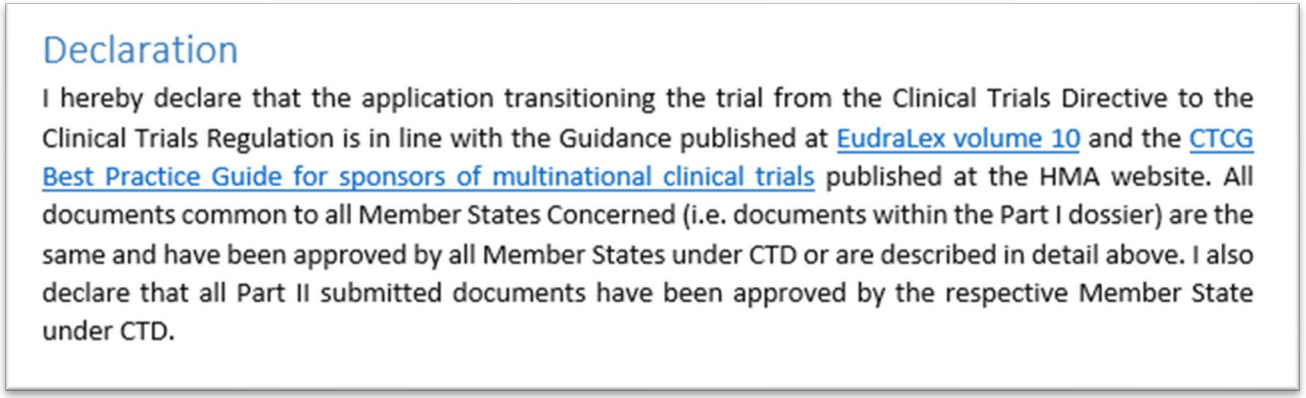
Bundesamt für Sicherheit im Gesundheitswesen
BASG

The Austrian Agency as RMS and MSC - NCA and Ethics Committees - relies on sponsors following the…

- the Guidance for the Transition of clinical trials from the CTD to the CTR
- the CTCG Best Practice Guide for sponsors of multinational clinical trials

and using the

- the Cover letter template



Declaration

I hereby declare that the application transitioning the trial from the Clinical Trials Directive to the Clinical Trials Regulation is in line with the Guidance published at EudraLex volume 10 and the CTCG Best Practice Guide for sponsors of multinational clinical trials published at the HMA website. All documents common to all Member States Concerned (i.e. documents within the Part I dossier) are the same and have been approved by all Member States under CTD or are described in detail above. I also declare that all Part II submitted documents have been approved by the respective Member State under CTD.

Validation Issues

All these issues were resolved!

Bundesamt für Sicherheit im Gesundheitswesen
BASG

- deficiencies in the cover letter → **use template and double check versions!**
- documents outside the „minimum dossier“ → **less is more!**
- inconsistencies EudraCT vs. CTIS data, especially trial sites → **double-check!**
- documents for IMPD (mostly SmPCs) and QP declaration

- addition of MSC that did not authorise under the CTD → **don‘t!!!**

- updates for legal references, duration of insurance or CTP training
  → **AT plans downgrade to recommendation for first SM Part II**

- proof of payment or billing information → **check national requirements**

Who and what to transition?

Just for clarification…

Bundesamt für Sicherheit im Gesundheitswesen
BASG

A trial can be ongoing under only one legislation – CTD or CTR.

- Sponsor should check if the trial has AT LEAST ONE SITE that will be active beyond 30 January 2025.
- If the trial needs to transition, you need to transition ALL countries where there are active sites AT THE TIME OF TRANSITION.

You cannot leave trial sites and countries active under the CTR while others are transitioned to the CTR.

Even if the sponsor hopes them to be closed before 31 January 2025.

Take-Home Message for Validation

The basis for an expedited procedure…

Bundesamt für Sicherheit im Gesundheitswesen
BASG

The transition application is reviewed during the **validation phase**.

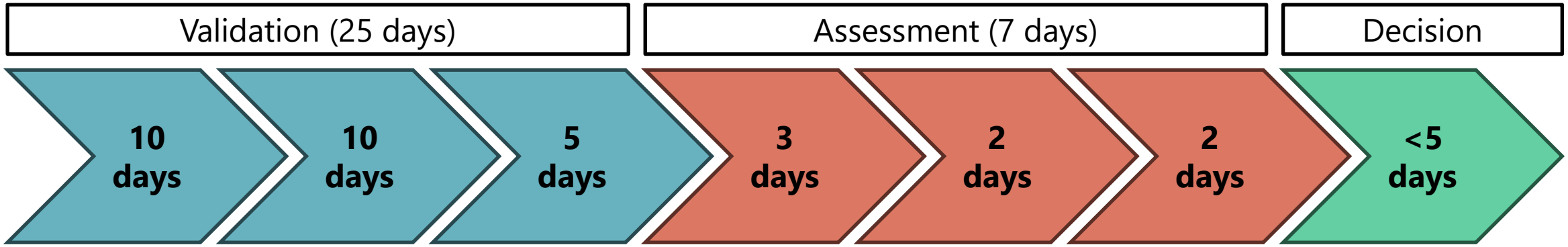
All **open issues have to be resolved** during validation to allow expedited Part I and Part II assessment.

Do not carry forward open issues into assessment phase!

Assessment

Transition is an administrative procedure!

Bundesamt für Sicherheit im Gesundheitswesen
BASG



- There should be no assessment necessary. All issues need to be resolved during validation.
- **It is our goal not to have any considerations.**
- So far we were successful as RMS and MSC!

National decision

„Ne bis in idem“

Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

BASG/AGES
Institute Surveillance
Traisengasse 5, 1200 Vienna

date:
department:
phone:
e-mail:
reference:

Notification of single decision according to Article 8 of REG (EU) 536/2014

The transition of the clinical trial is approved.

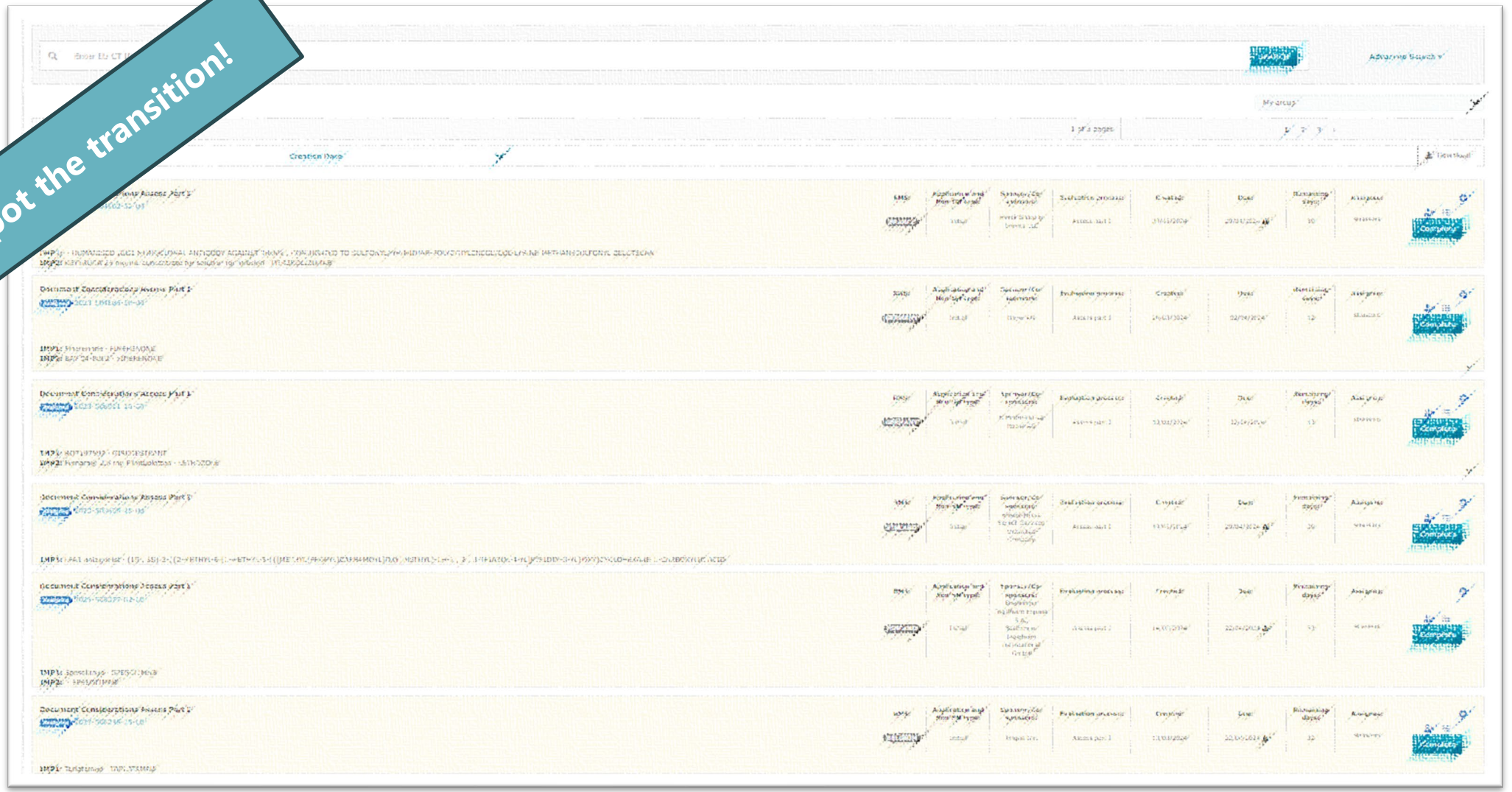
The further conduct of the trial now follows the rules of Regulation (EU) 536/2014.

The transition procedure is concluded. No formal legal decision will be issued.

Our challenges - Overview

Not seeing the tree for the forest…

Bundesamt für Sicherheit im Gesundheitswesen
BASG



Our challenges – Ethics Committee and Part II

The Austrian system of EC involvement

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Task	Validation	Part I	Part II
Circulate DAR	-	NCA	-
Document considerations Assess Part I	NCA + **EC subt.**	**NCA + EC subt.**	**EC (assigned)**
Consolidate considerations	NCA	-	-
Submit RFI	NCA	-	-
Assess RFI response	NCA + **EC subt.**	-	-
Submit conclusion	NCA	NCA	**EC EC (assigned)**

„Assign“ function does not allow comments or change of timelines.

Our challenges – Reports

Making the system happy!

Bundesamt für Sicherheit im Gesundheitswesen
BASG

- **Administrative draft report**

  → needs to be reworked because prepopulation is inadequate

- **Quality draft report**

  → standard text; basis for future modifications

- **Conclusion draft report**

  → standard text; basis for future modifications

- **Final assessment report without quality (mandatory)**

  → from DAR via redaction tool

- **Final assessment report quality (mandatory)**

  → from DAR via redaction tool

- **Placeholder for publication**

Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Transitioning a trial with reference to an external IMPD-Q

When and how to transition the IMPD?

Bundesamt für Sicherheit im Gesundheitswesen
BASG

Guide to sponsors on requirements for updating Part I documents in line with the CTR at the time of the first SM Part I (draft for publication)

	a) ***Planned inclusion of additional Member State concerned*** *(CTR Article 14)*	b) ***Recruitment and/or treatment/IMP administration ongoing in at least one MSC included in the transition application***	c) ***Declared closed treatment/IMP administration in all MSCs****, i.e. remaining procedures restricted to* ***trial-specific follow-up interventions***
AxMPD, IMPD	Update documents after IMP/AxMP harmonisation (and upload in CTIS) in line with revised Recommendations at EudraLex Volume 10[7]	Update documents after IMP/AxMP harmonisation (and upload in CTIS) in line with revised Recommendations at EudraLex Volume 10[3]	-
	As agreed for the transition trial submitted in the initial application, there is no need to split the IMPD approved under CTD into separate documents IMPD-Q and IMPD-SE	As agreed for the transition initial CTR application, there is no need to split the IMPD approved under CTD into separate documents IMPD-Q and IMPD-SE	

Transition with reference

Bundesamt für Sicherheit im Gesundheitswesen
BASG

At the time of transition:

- Instead of an IMPD provide a „justification for no IMPD upload“ and explain the situation.
- Make a reference via „associated trials“, if possible at that time.

At the time of first SM Part I:

- Make a reference via „associated trials“, if possible now.
- If not possible, then go for an „IMPD-Q-only“-application.

Transition with IMPD-Q-only

Bundesamt für Sicherheit im Gesundheitswesen
BASG

At the time of transition:

- Instead of an IMPD provide a „justification for no IMPD upload“ and explain the situation.
- **No IMPD-Q-only applicaten required at the time of transition!**

At the time of first SM Part I:

- Perform and „IMPD-Q-only“ application according to 2.15 of Eudralex Vol. 10 Q&A.
- Legal timelines of the SM will be used for the IMPD-Q-only application.

IMPD-Q-only applications can only be done for the quality part (manufacturing CCI).

The trial sponsor needs to have full knowledge about the benefit/risk profile of the IMP to fulfil their legal obligations.

Thank you for your attention!

Questions?

Austrian
Federal Office for
Safety in Health Care
BASG

Stefan Strasser, MD

Head of Clinical Trials, Institute Surveillance

BASG -
Austrian Federal Office for Safety in Health Care

Traisengasse 5
1200 Vienna
T: +43 (0) 50555 36827

stefan.strasser@ages.at
www.basg.gv.at