

PHARMACOVIGILANCE AGREEMENTS PVA/ SDEA

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DISCLAIMER

The views expressed in this presentation is my views and it doesn't reflect the views of BHC

AGENDA

Introduction

PV person Responsibilities

Types of PVA

Training

SDEA/PVA tracking

Partner Compliance/ KPI



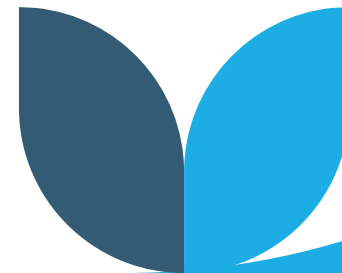
INTRODUCTION

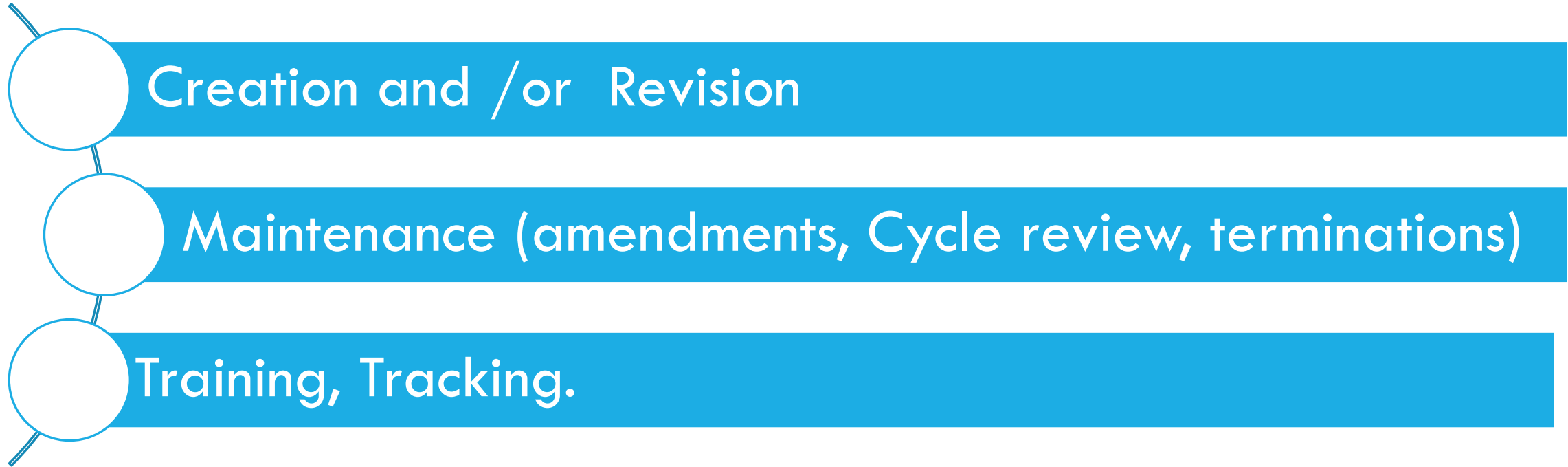
A **“binding contract”** is any agreement that's legally enforceable. That means if you sign a binding contract and don't fulfill your end of the bargain, the other party can take you to court.

Safety Data Exchange Agreement

Legal written contracts ensuring that all safety data regarding a licensed product makes its way quickly and reliably back to the marketing authorization holder.

An agreement to cover the pharmacovigilance responsibilities of a MAH and its partner, where the MAH has granted to the partner extensive rights to commercialize/ promote/ do service and delegated the part or bulk of its pharmacovigilance activities to the partner, including the reporting of adverse events to the relevant regulatory authorities.



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- Creation and /or Revision
 - Maintenance (amendments, Cycle review, terminations)
 - Training, Tracking.

PV PERSON RESPONSIBILITIES

WHICH AGREEMENTS/ PARTNERS?

- PV service Provider agreements.
- Licensing and supply agreements, Inter Company agreement (ICA)
- Distribution agreements.
- Promotional/ marketing agreements.
- Other master service agreements:
 - Translation service.
 - Social media pages/ website/ other electronic services
 - MSP, PSP



How could I track / learn about these contracts/ partners?

IMPORTANT TIPS

Add

Essential PV wording at master service agreement (DA, ICA, Supply, etc.)

Add

Clause “separate SDEA shall be executed as applicable”.

Add

Termination and termination surviving clause.



TYPES OF PVA



PV clause/ wording at MSA.



Abridged or Abbreviated agreements.



Full safety data exchange agreement/ SDEA



PVA/ SDEA amendment.



Termination agreement/ TA



“

**HOW WOULD I CHOOSE THE
TYPE OF AGREEMENT?**

”

PV CLAUSE/ WORDING OR ABBREV. SDEA.

- Distribution agreement (logistic)
- Social media pages/ website/ other electronic services.
- Translation services



What to
report



When to
report



Where to
report



Acknowledgment/
Reconciliation



Remember!
Train your partner



FULL SAFETY DATA EXCHANGE AGREEMENT (SDEA)

- Licensing and supply agreements
- Marketing and promotional services.
- Distribution agreement (Authorized agent)

RESPONSIBILITIES

- Exchange of AE reports, Other Safety Information deriving from special situations, Incomplete cases, Pregnancy reports, Solicited sources of individual case safety reports and clinical studies. Follow-up reports.
- Acknowledgement of receipt/Reconciliation.
- Regulatory Submission to NCA
- Training
- Literature Review global/local.
- Safety Signal Monitoring/ management of AE Reports
- PSUR preparation

CONT. RESPONSIBILITIES

- RMP and additional RMM preparation and dissemination.
- Product technical complaint (PTC) associated with an AE, recalls and other safety actions
- RSI (PIL, CCDS)
- Safety issues, inquiries from Regulatory Authorities
- Local QPPV or LSR
- PSMF exchange
- Audit
- Internet monitoring



CHANGE IN
PARTNERSHIP
MODEL



MASTER SERVICE
AGREEMENT
AMENDMENT



CHANGE IN LOCAL
REGULATION



CHANGE PV
CONTACT DETAILS



CHANGE IN
PRODUCT LIST

PVA/ SDEA AMENDMENT.

TERMINATION AGREEMENT

Terminate agreement with no surviving PV clause

MSA is terminated or expired and no possibility to receive AE/ADRs.

DA terminated or expired + no product supply (e.g last shipment expired for more than 6 months)

Terminate agreement with surviving PV clause

MSA is terminated or expired, and partner may receive AE/ADRs on your behalf.

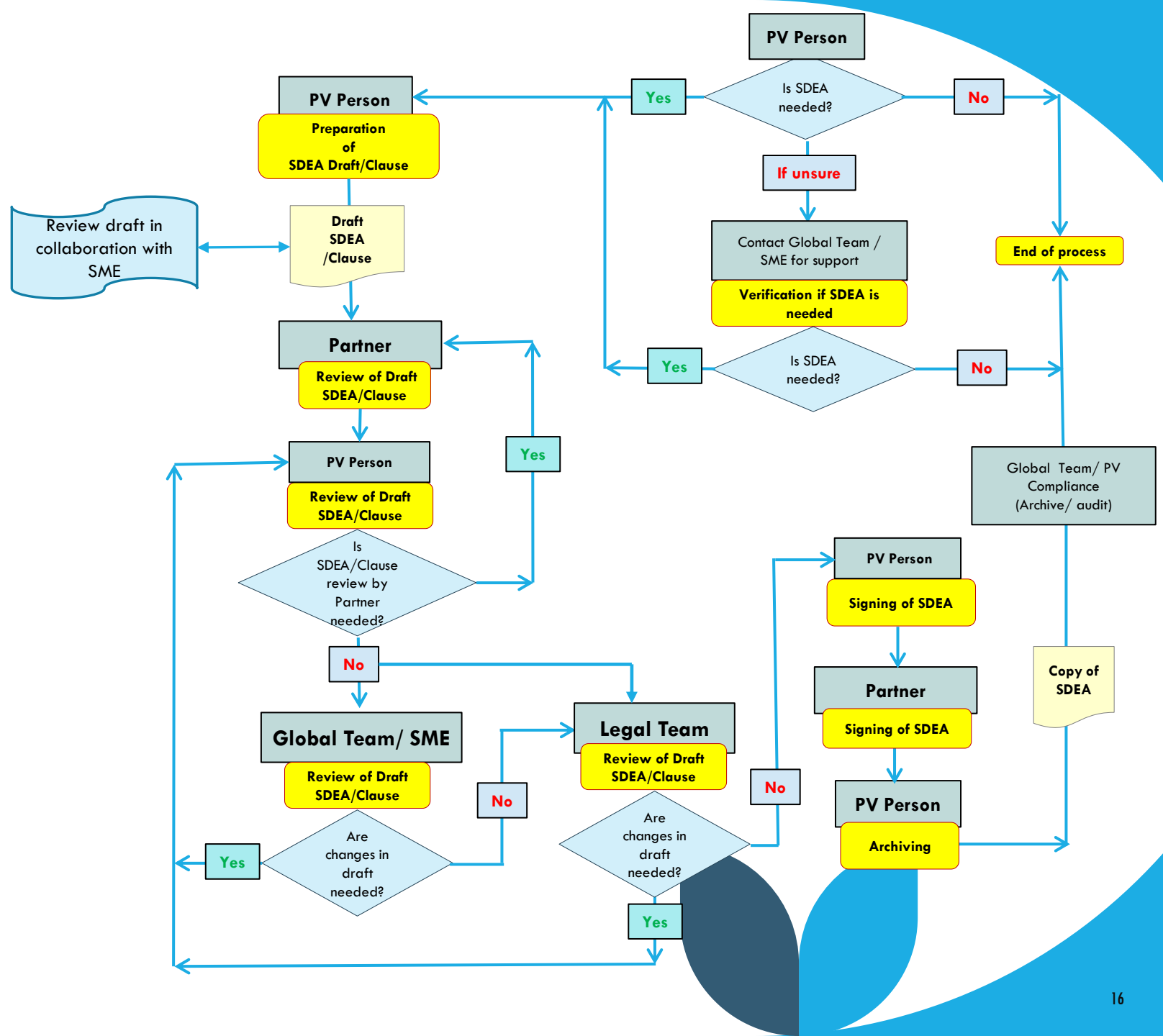
DA terminated or expired during active product supply.

Include termination clause in the MSA or SDEA to enforce termination agreement execution.

PV surviving clause extends safety exchange to mitigate the risk of missing safety reports.

PV surviving clause remains \geq last expiry date of MAH's product + 6 months.

SDEA DRAFT AND REVIEW FLOW CHART



TRAIN QPPV AND PV PERSONNEL ON SDEA

TRAIN PARTNERS TO FULFILL THEIR TASKS AND RESPONSIBILITIES AS PER SDEA.

TRACK AND ARCHIVE TRAINING RECORDS FOR PV TEAM AND PARTNER.

TRAINING ASSESSMENT AND SUCCESS CRITERIA SHOULD BE DEFINED AND RECORDED.



TRAINING

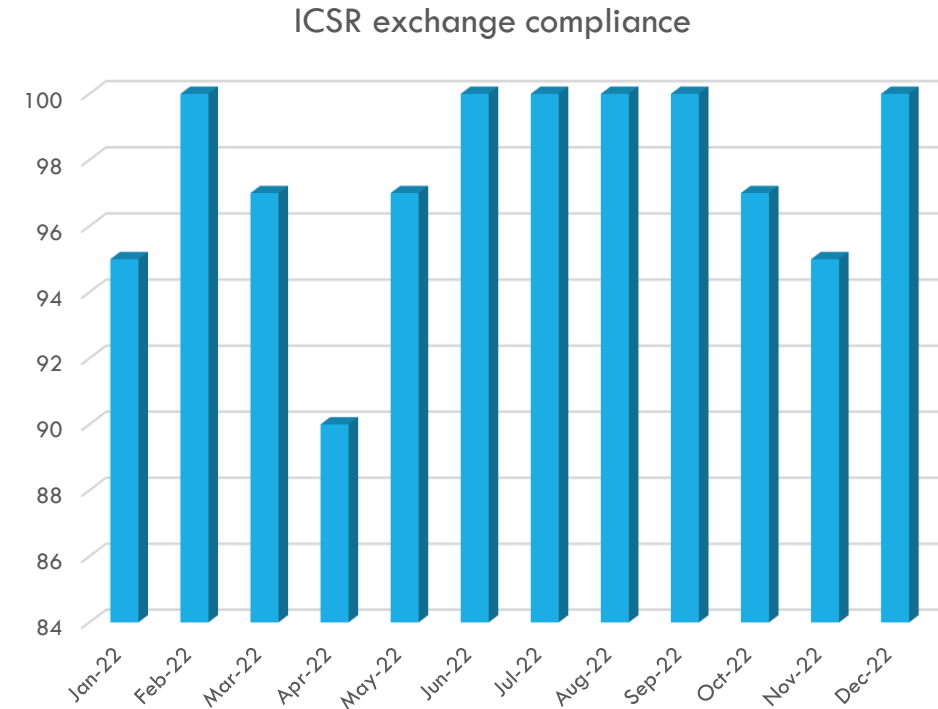
SDEA/ PVA TRACKING



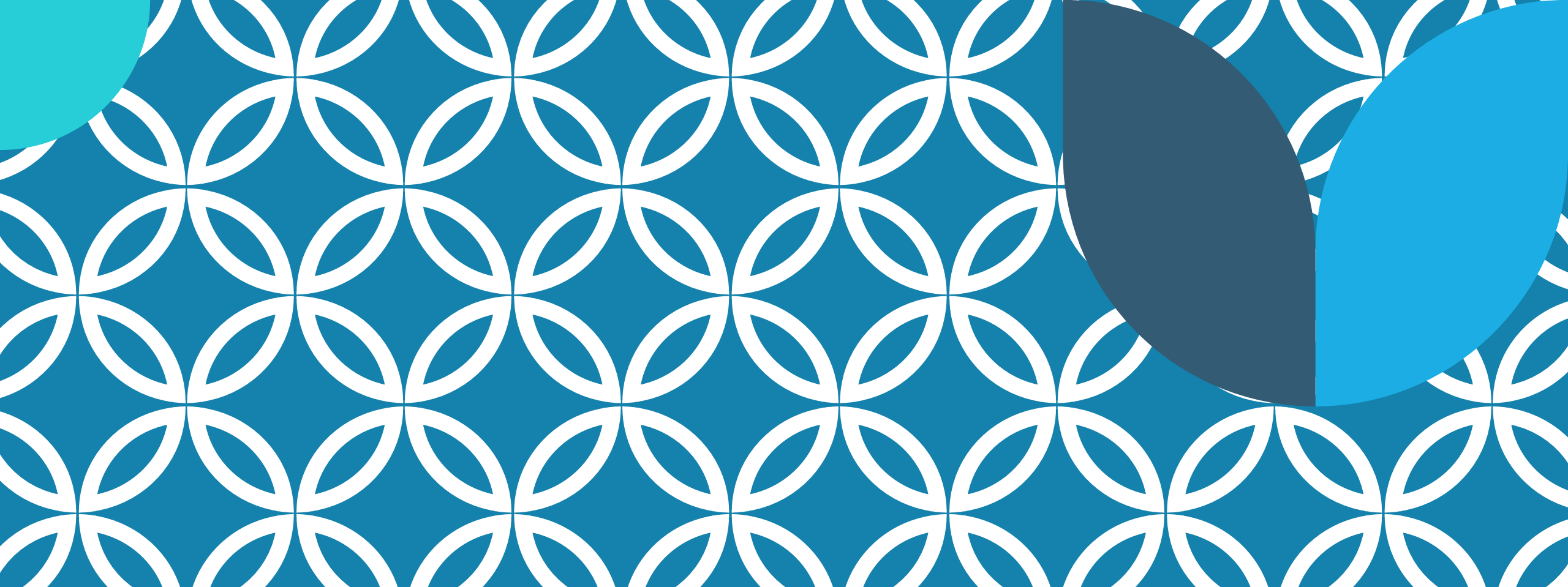
- Different partners/ legal entities.
- MSA effective date, expiry date, renewal/autorenewal, related addendums.
- Type of PVA (PV clause, SDEA, abbrev SDEA).
- SDEA status (ongoing, effective, terminated, terminated with surviving clause, etc.).
- SDEA execution/ effective date & Next SDEA revision.
- PV responsibilities / each partner.
- ✓ ICSR exchange timeline.
- ✓ Regulatory submission responsibilities
- ✓ PSUR, RMP, RMM/ aRMM responsibilities.
- ✓ Literature screening and NCA website screening.
- SDEA contact details / function.
- Partner trainings.
- Notes for amendments/ next revision.



- ✓ ICSR exchange compliance.
- ✓ ICSR submission compliance.
- ✓ PSUR/ RMP submission compliance.
- ✓ New and updated PV regulation exchange compliance.



PARTNER COMPLIANCE/ KPI



THANK YOU

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