

How SA is Filling the Gaps in Pharmacovigilance



*Programmatic Management and Drug Safety
Monitoring*



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Introduction & Overview



A journey with
pharmacovigilance
in its evolution to
Improve medicine safety



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Pillars of Pharmacovigilance



PHARMACOVIGILANCE

Improved patient care and safety

Detection

Assessment

Understanding

Prevention

interventions

Assessment of the effectiveness of these interventions



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Common methods in PV



Methods

Spontaneous
reporting

aDSM

Active
monitoring

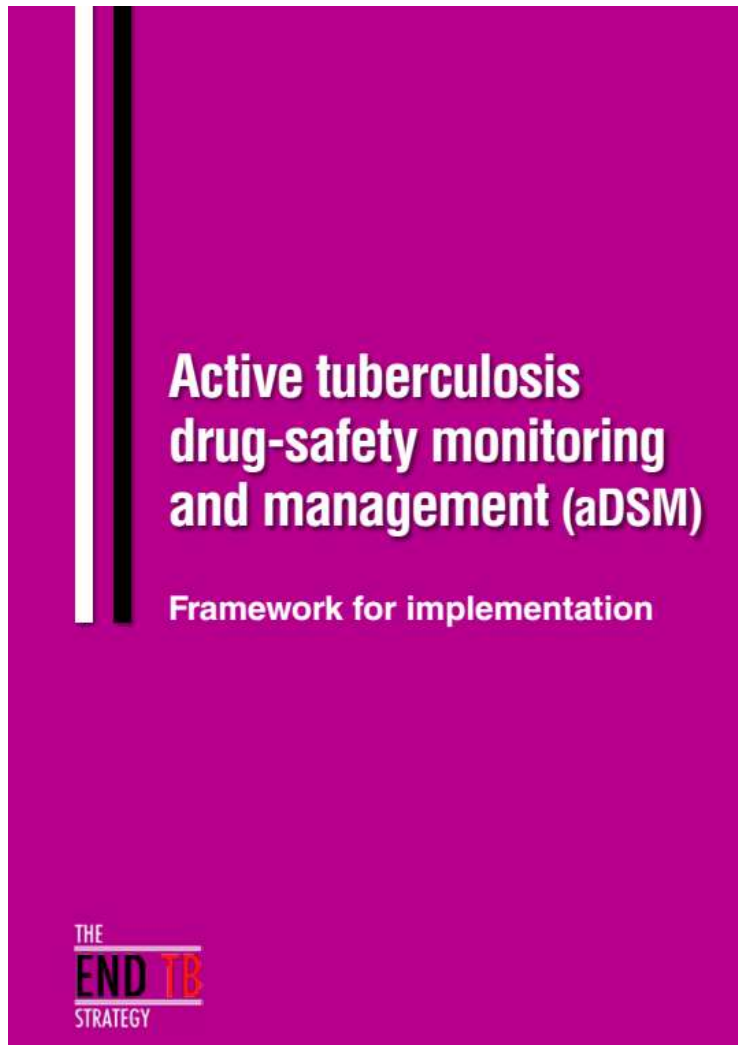


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aDSM



- **a**-active tuberculosis
- **D**-Drug
- **S**- Safety
- **M**-Monitoring & Management



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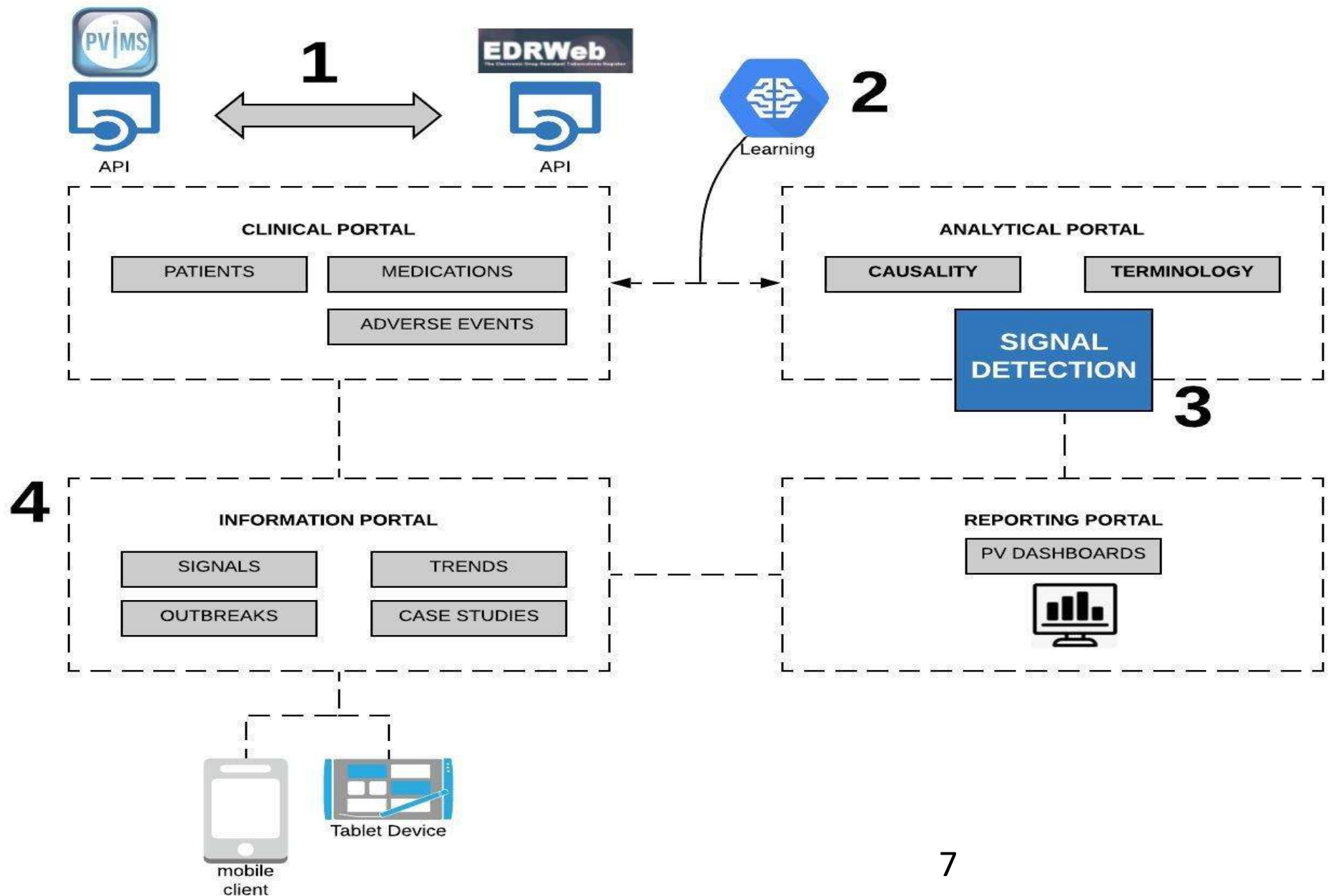
Evolution for PV



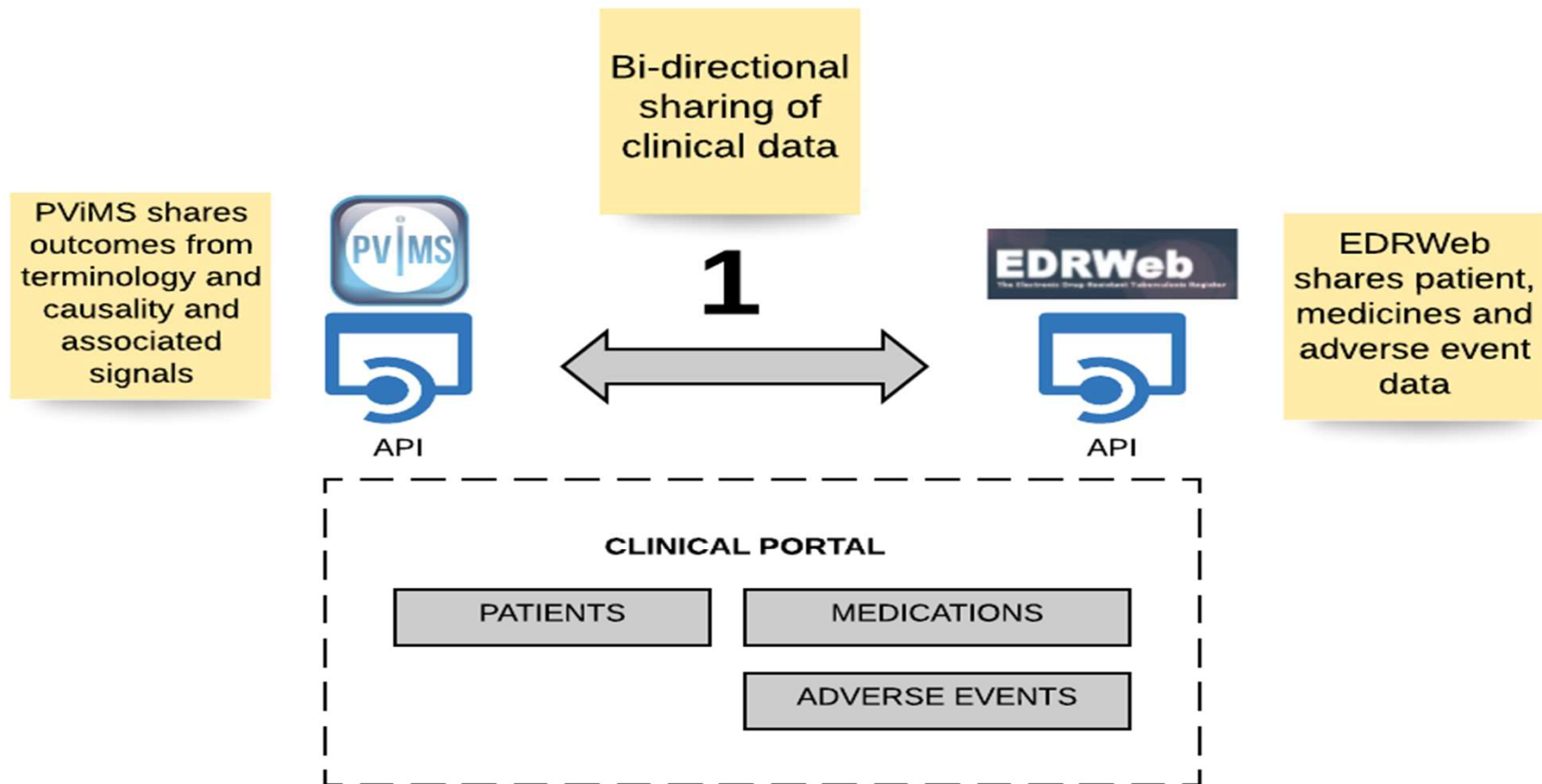
Event	Pharmacovigilance Development
Est. of PV office in Cape Town by MRA 1987	PV officially starts in SA
Full membership of the International Drug Monitoring Centre (WHO) 1992	Together with Morocco the first 2 countries in Africa
2003/4 roll out of ARVs	Appointment of National PV Coordinator at MRA/MCC, now SAHPRA To develop the PV Unit & Train HCWs country wide on what is PV
D4T lipodystrophy/lactic acidosis	Increase focus on Programmatic PV. Training on what, where and how to report. Moved from SR to TSR
NVP vs EFV 2010 /12	EFV to be used in pregnancy . Birth of the Pregnancy Registry
Registration, SJS, Liver toxicity	Need for programmes to have their own PV Appointment of Director at NDoH PV for PHP 2014/2015
DTG and neural tube defects 2018/2019	Delay in the roll out of DTG Funds for active surveillance moved to expand and strengthen preg registry
COVID, New TB Drugs and regimens	EPI programme strengthen, NPC Active surveillance for DRTB, Electronic capture on all medicines (SAHPRA web and app)



EDRWeb and PViMS Integration



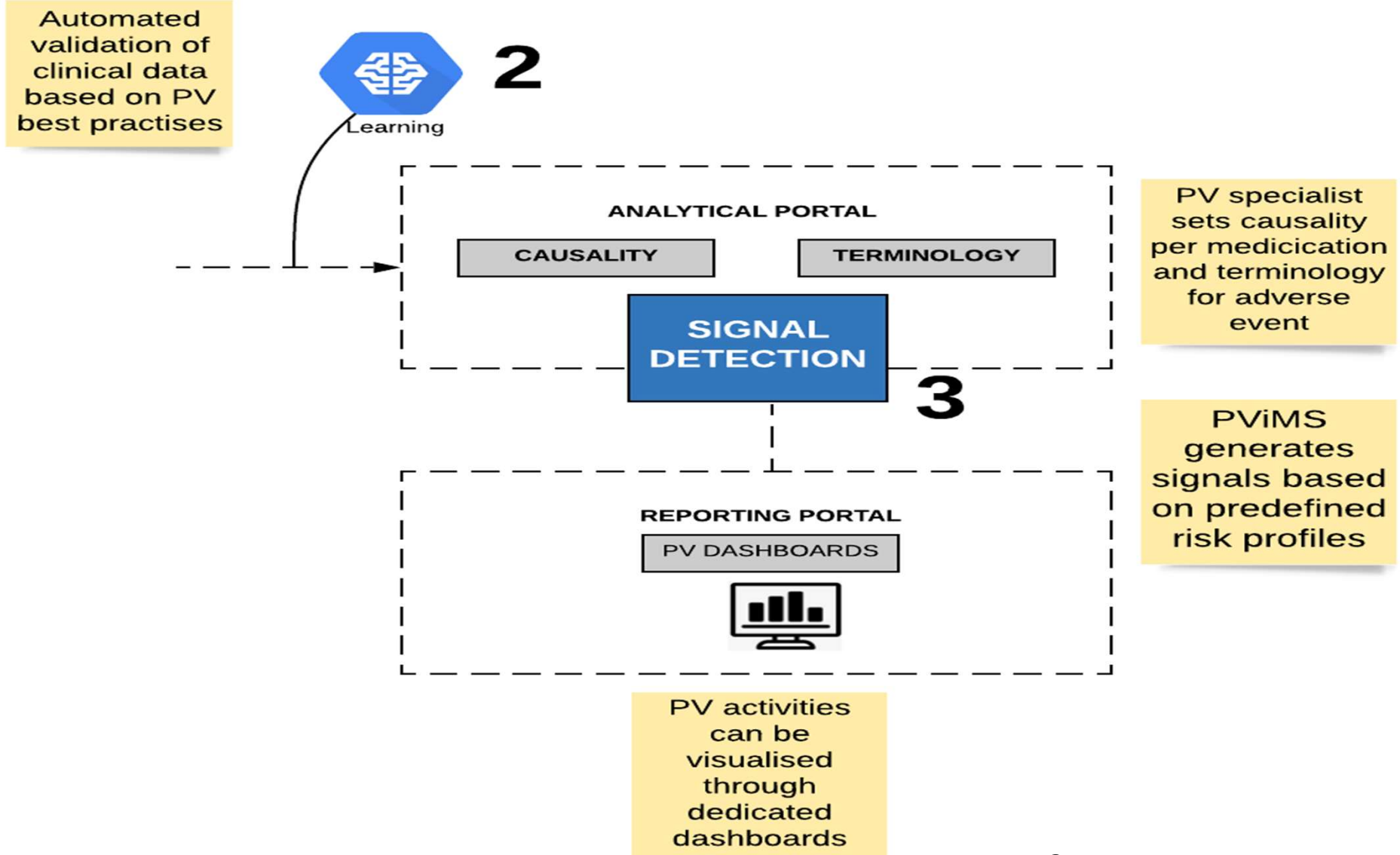
CLINICAL



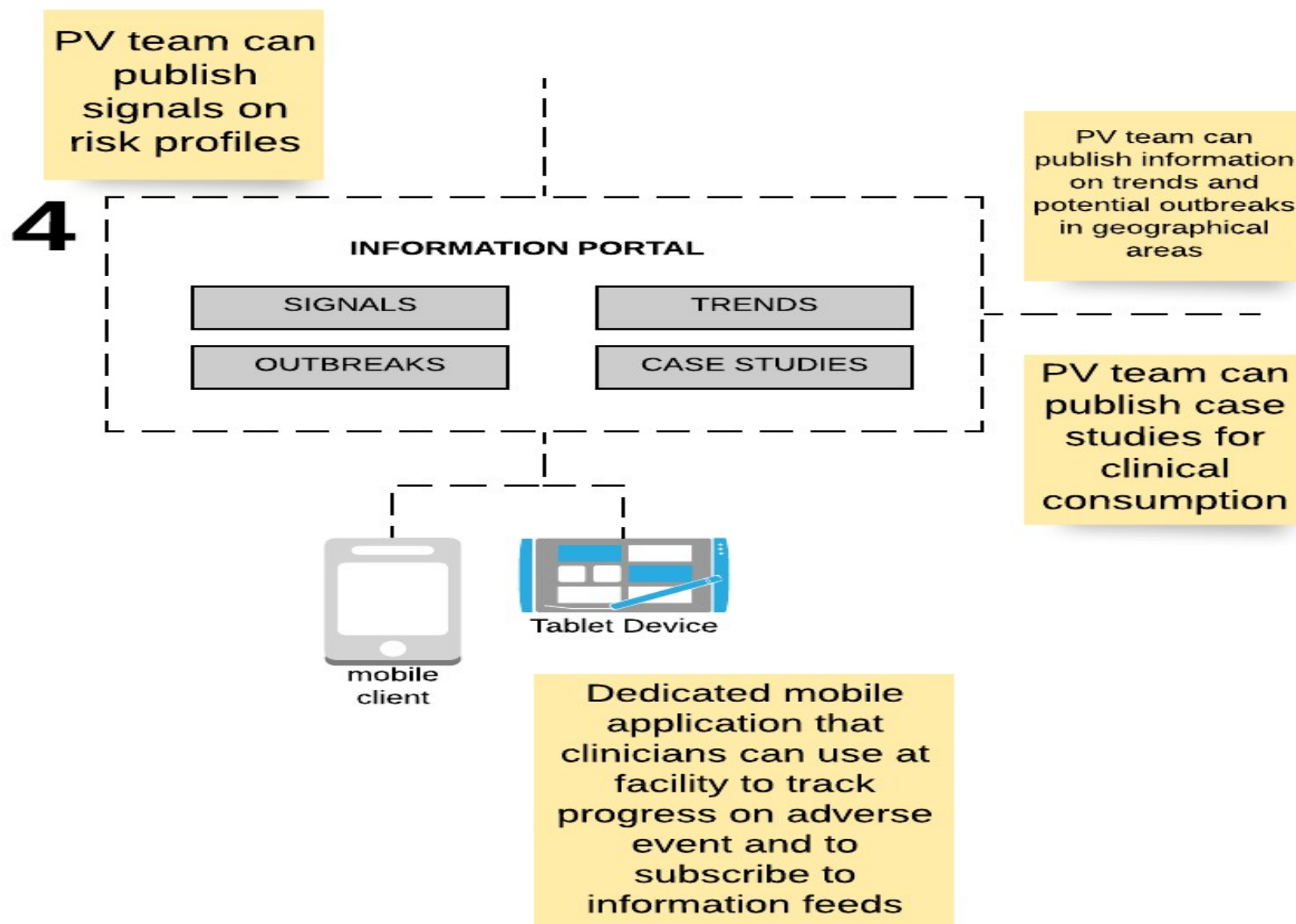
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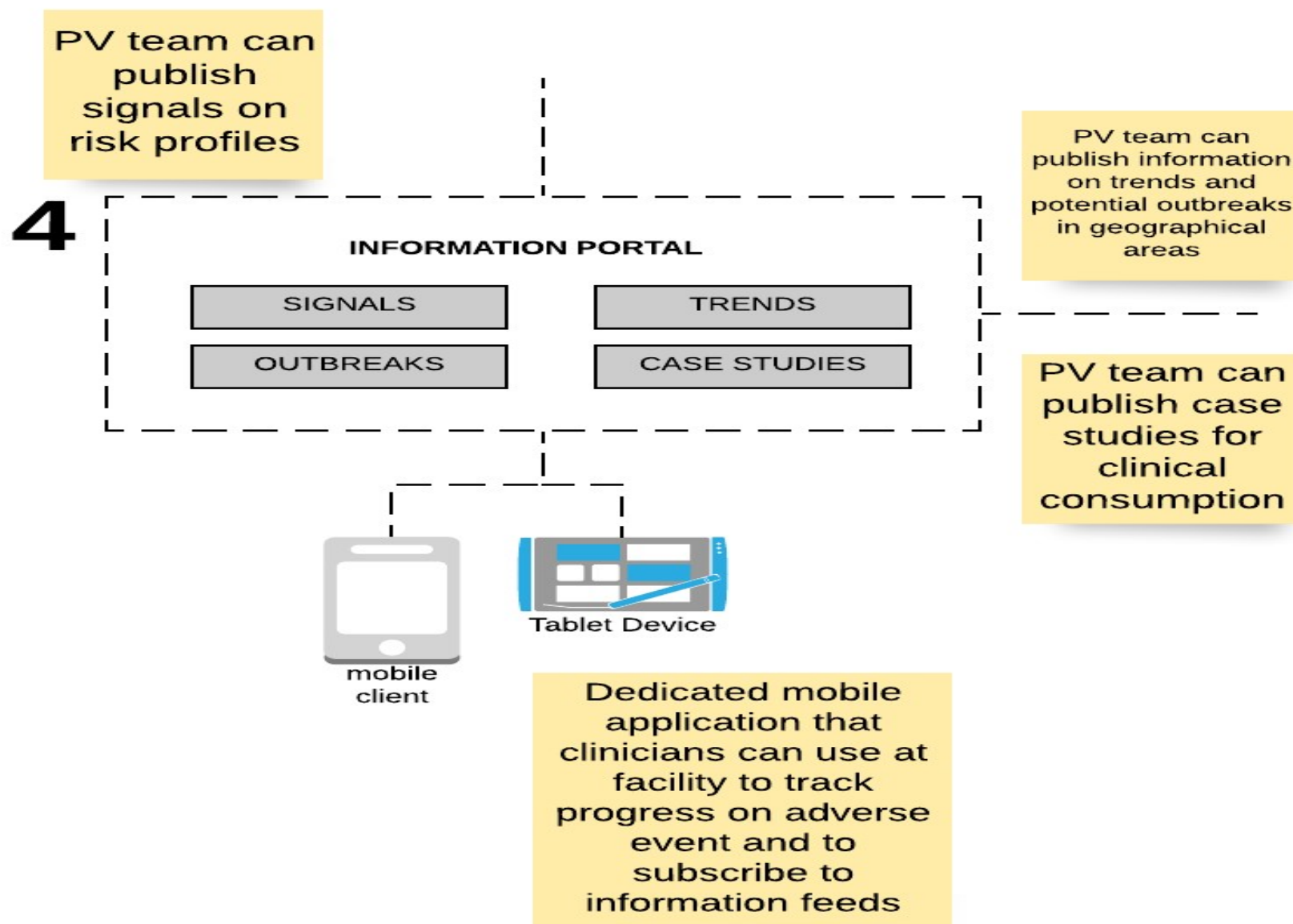
ANALYTICAL



INFORMATION



INFORMATION



INFORMATION DASHBOARD



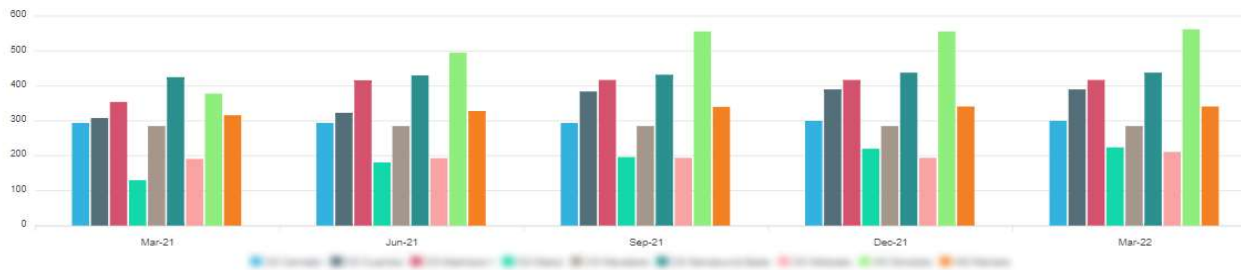
Please select a cohort below...

ADSM HIV TLD Cohort 17

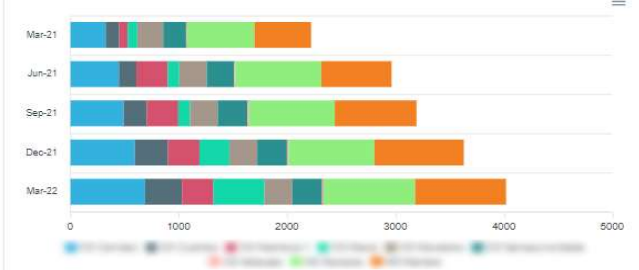
ADSM HIV TPT Cohort 9

ADSM Vaccinations Cohort 9

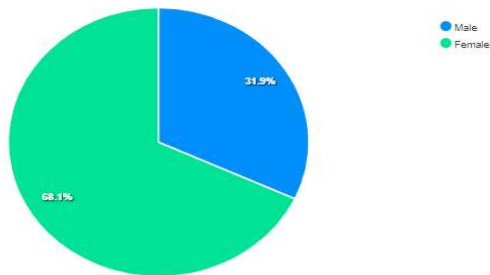
Enrollment-cumulative



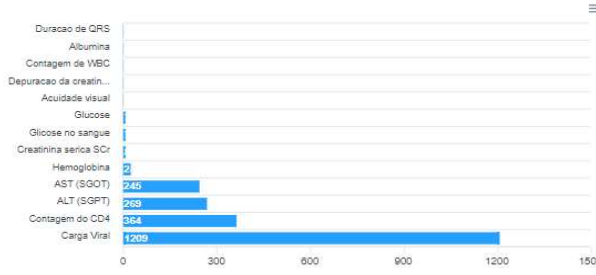
Follow Up Visit-cumulative



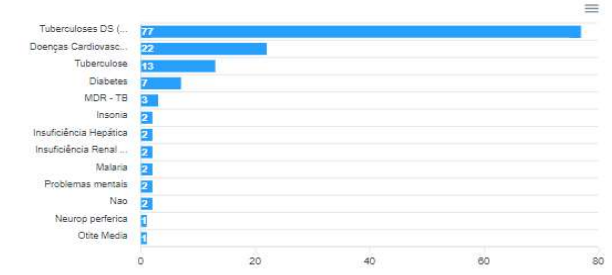
Gender-distribution



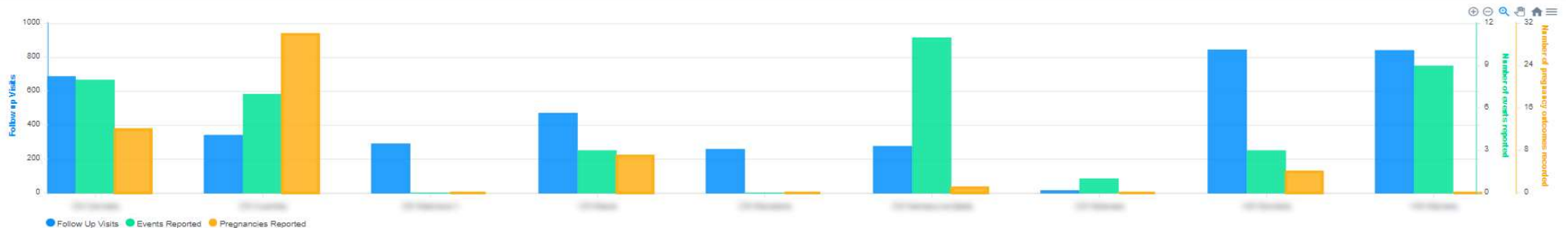
Lab Test-distribution



Condition-distribution



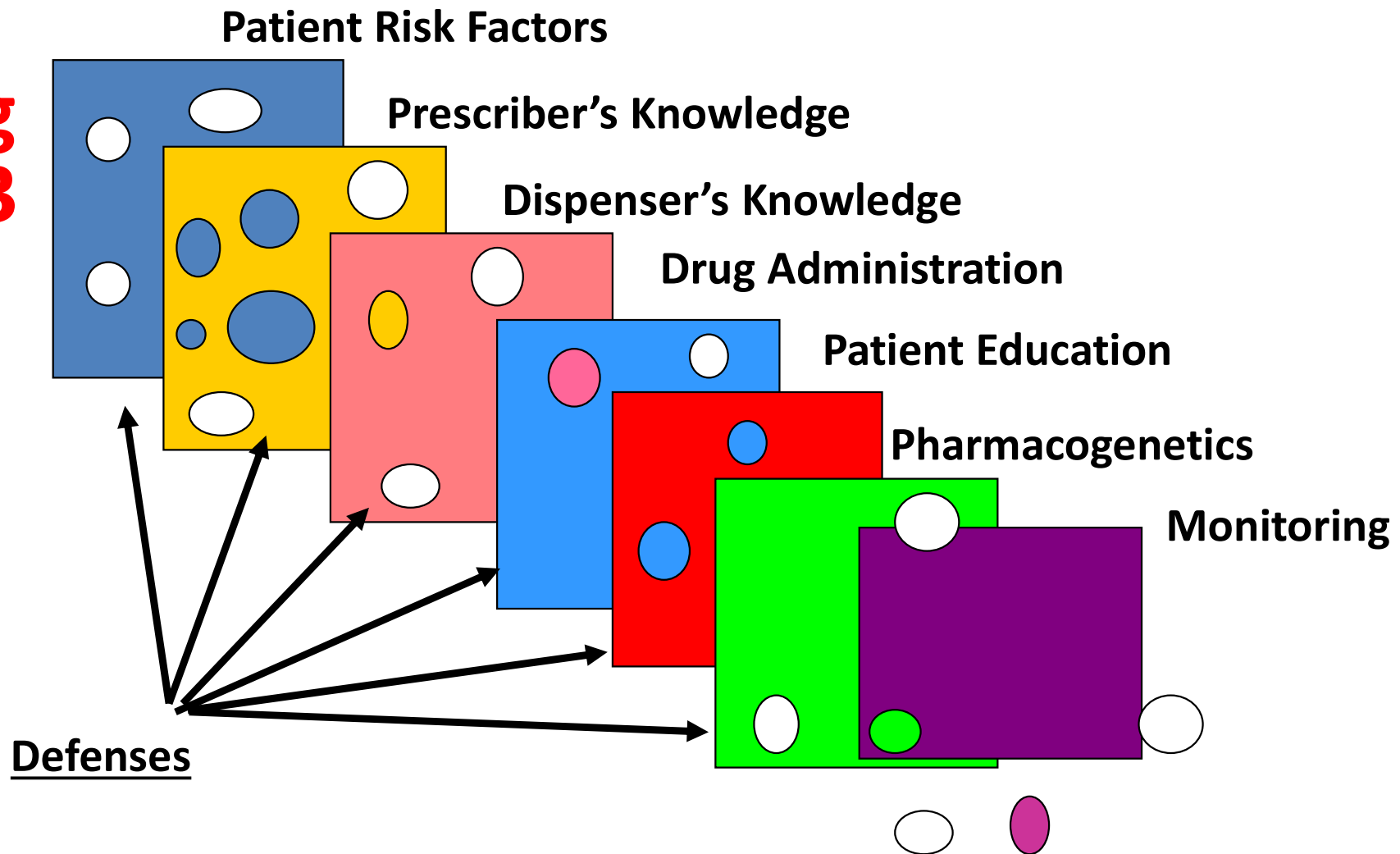
Follow-up visits and AEs reported per facility



Possible Points of Defense to prevent ADRs



**Drug
1,2,3**



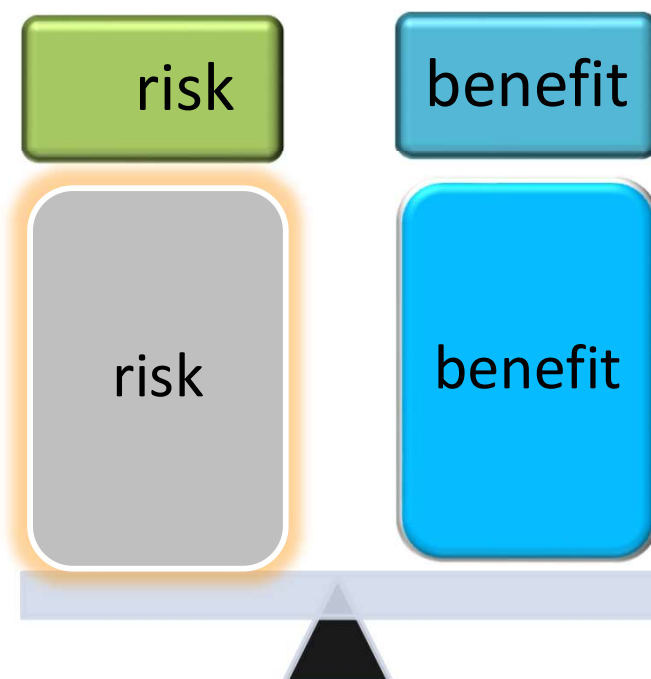
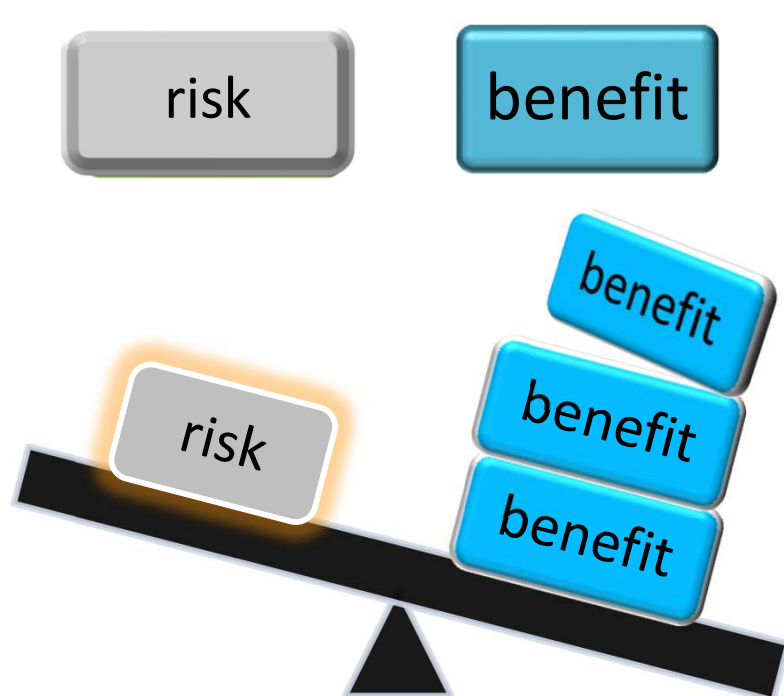
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Modified from Hansten et al 1990

ADR

- benefits >>> risks
- greatest achievable margin
- the individual patient and population as a whole



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Thank you for your attention!

