EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Good pharmacovigilance practices for the European Union (EU-GVP)

PRAC June 2017

Presented by Priya Bahri
EU-GVP Editor, European Medicines Agency

News since summer 2016:

Introductory Cover Note Updates: Q1 2017 ✓, Q3 2017, Q4 2017

Process **M**odules:

PSMF Rev2 Q1 2017
RMP Rev2 Q1 2017
ICSR Rev2 * ✓ Q3 2017
[VI.AddI Dplcts] [*] 2017
[PSUR Rev2] [*] Q3/4 2017
PASS Rev2 * 2016
Signals Rev1 * ✓ Q3 2017
IX.AddI Stats * ✓ Q3 2017
Comms Rev1 * ✓ Q3 2017
RMM Rev2 Q1 2017

Population- or Product-Specific Considerations:

Biologicals * 2016
[Children] [*] Q3 2017
[Preg/breastfdg women] [*] Q4 2017
[Older patients] [*] Q3 2017

Annex I:

DEF Rev4 no* ✓ Q3 2017

Annex II

- Templates * ✓ Q3 2017

Annex III

- Guidance prior to GVP

Annex IV

- ICH guidance

Annex V

- ABBREV Rev1 Q3 2017

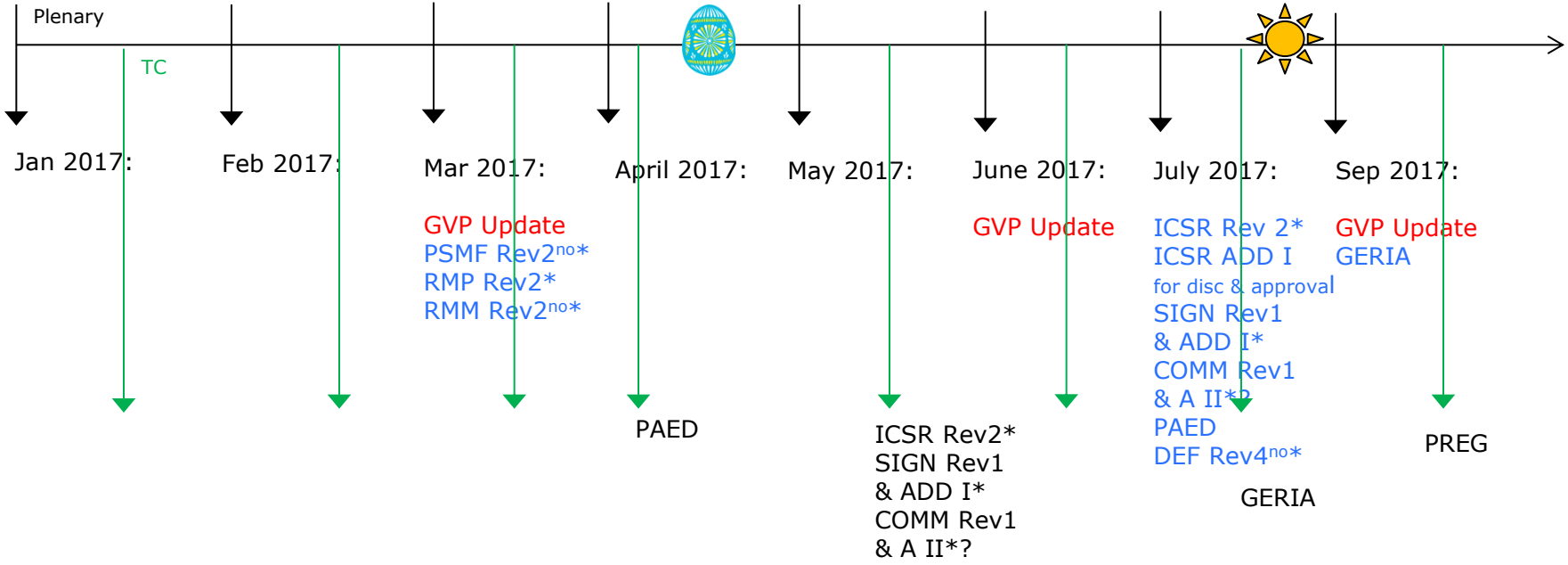
GVP Archive

Links to non-GVP guidance

Symbols:
✓ Under finalisation
* Public consultation closed
[] Drafting ongoing
[*] Public consultation planned
no* = no public consultation

Timelines for PRAC 2017

PRAC ORGAM for discussion and for approval



Symbols:
* = post-public consultation
no* = no public consultation

PRAC 2017

Revisions published as final up to Q2/17:

PSMF Rev 2 no*
RMP Rev 2*
RMM Rev 2 no*

Finalisation post-public consultations ongoing:

ICSR Rev 2*
SIGN Rev 1*
SIGN ADD I Rev 1*
COMMS Rev 1*

Ongoing revisions:

DEF Rev 4 no*

Under development:

PSMF Rev 3
ICSR Rev 3
ICSR ADD I
PSUR Rev 2
RMM Rev 3
PREG
PAED
GERIA

Symbols:
* = post-public consultation
no* = no public consultation