Surveillance and vigilance What do regulators and notified bodies expect?

EFORT Implant & Patient Safety Initative
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TÜV SÜD

Mehr Sicherheit.
Mehr Wert.

Choose certainty.
Add value.

Disclaimer

This presentation is based on information available as of today and prepared to my best knowledge as subject matter expert.

This presentation presents my personal understanding of the medical device requirements in Europe and is not reflecting the view of TÜV SÜD PS.

Important changes & improvements*

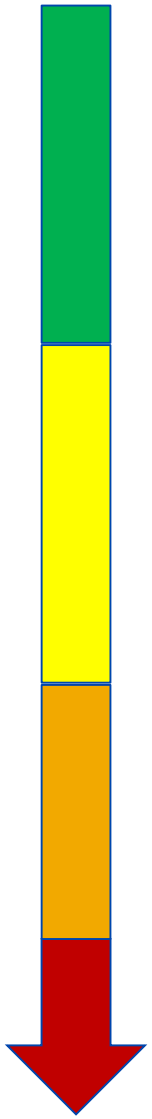
- Stricter pre-market control
- Oversight of notified bodies
- Inclusion of products w/o medical purpose
- EUDAMED database
- Implant card
- Rules on clinical data and clinical investigations
- Data about real-life use of devices

* Source: http://ec.europa.eu/growth/tools-databases/newsroom

Data Quality for Orthopedic Implants

- **Historical data** often medium to low quality
- Limitations of **published literature** (study design, endpoints, bias, data gaps,…)
- Limitations of **Post Market Clinical Follow-Up (PMCF) Studies**
  - extrapolation to Real World Data
- **Registries**
  - ✓ Validation? IMDRF Guidance?
  - ✓ Data on safety and performance?
  - ✓ Ad-hoc Reports

Data Quality for Orthopedic Implants



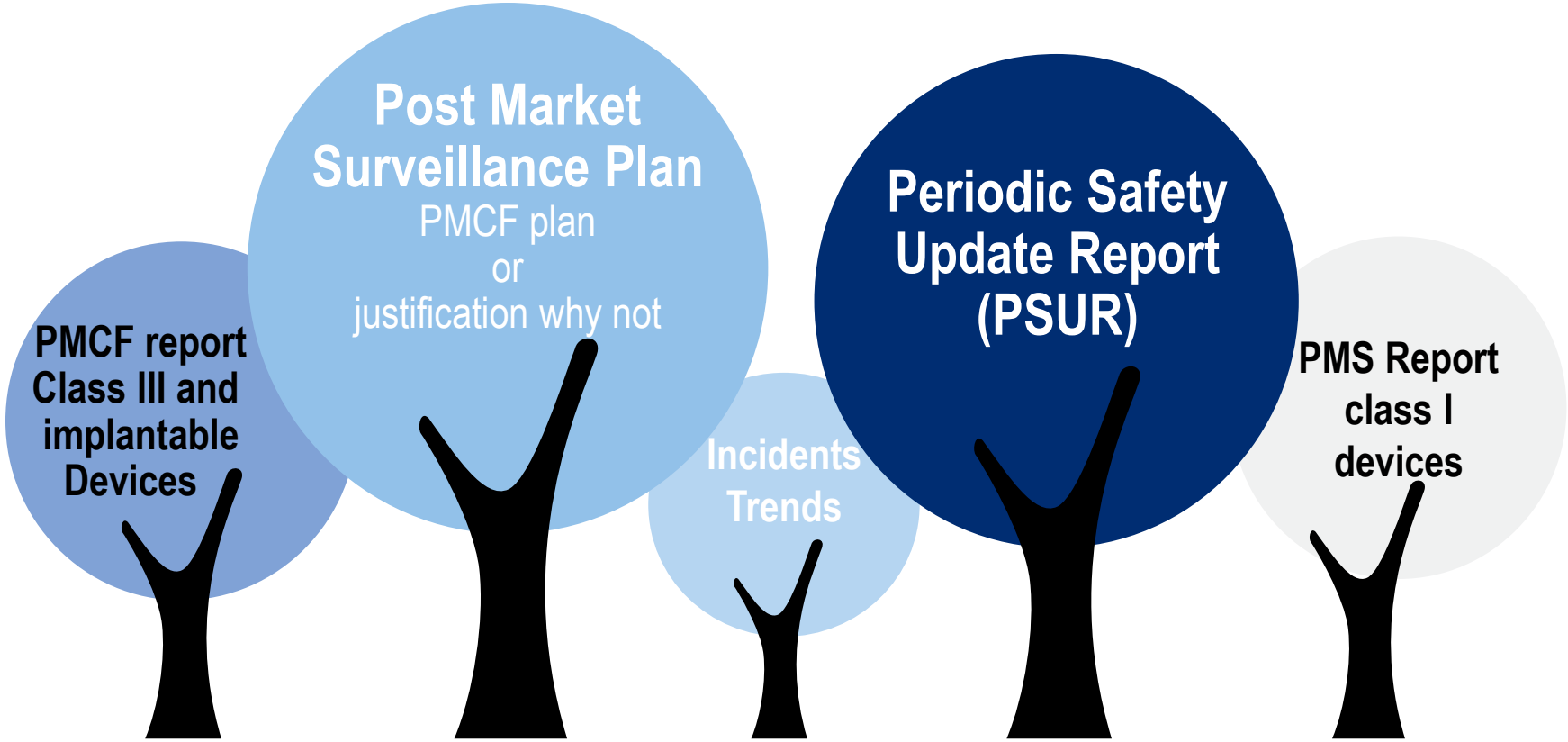
- High quality clinical studies, covering all device variants, all indications, all patient (sub-) populations, full device lifetime
- High quality studies with some gaps that can be closed with other evidence
- High quality data from Registries and/or other high volume Real World Data

- Studies with potential methodological flaws but where data can still be quantified and acceptability justified
- Common Specifications
- Reliable data on equivalent devices

- State-of-the-Art evaluation (no safety and performance concerns for similar devices
- Sales, complain and vigilance data (high volume)
- Case reports

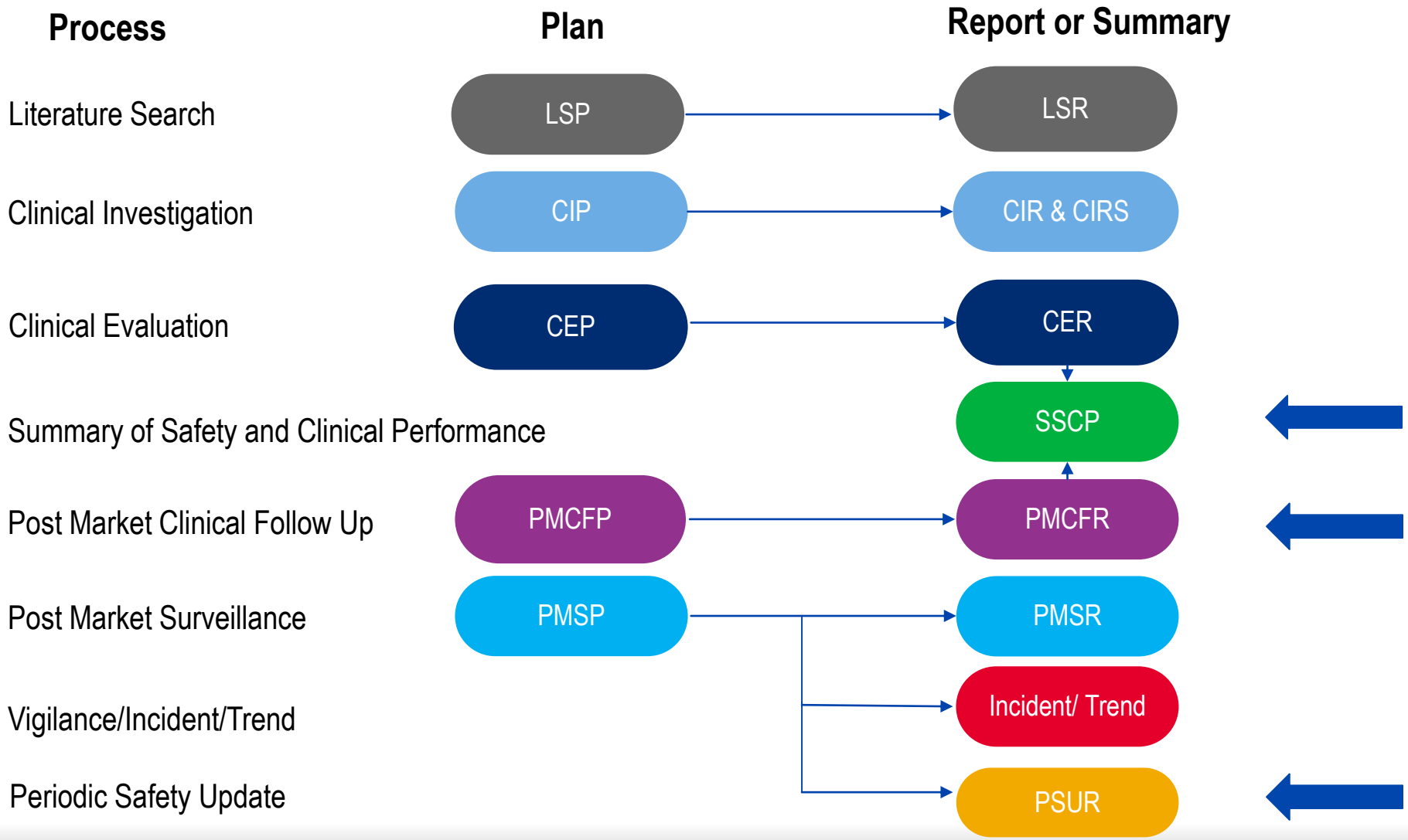
- Usability testing (e.g. cadaver lab), animal studies
- Bench testing, compliance with standards

Major elements of PMS



Article 120.3: However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

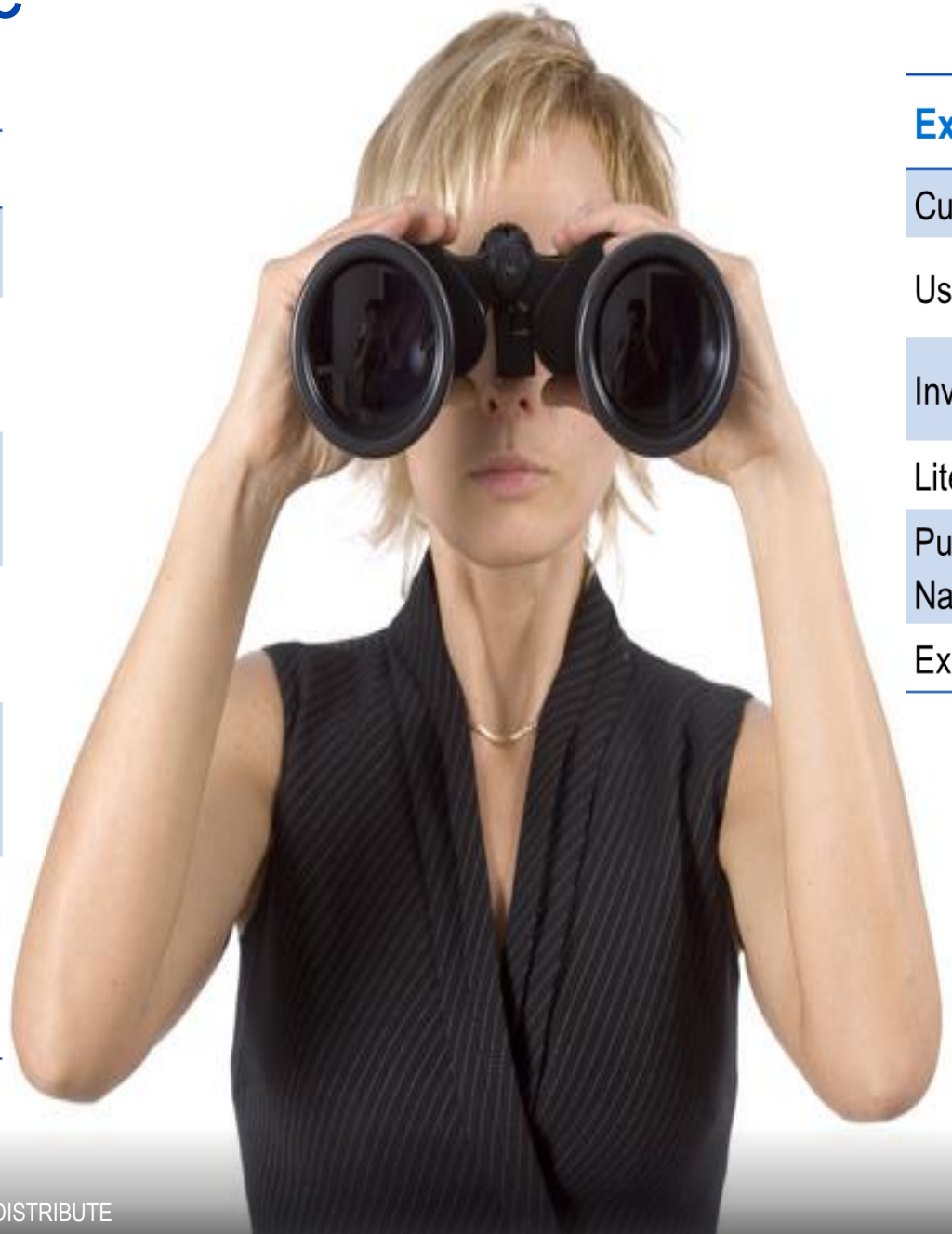
Clinical Aspects – Processes, Plans (P), Reports (R), Summary (S)



Post-Market Surveillance

Examples of ACTIVE Methods

- Planned Customer Surveys
- Prospective and retrospective Post-market clinical investigations or studies
- Company-supported Investigator-Sponsored Studies (ISS)
- Extended clinical investigations
- Company registry based on the output of the risk management file and the CER
- Planned Analysis of Regional or National Device Registries - Hospital Databases, Registries



Examples of REACTIVE Methods

- Customer Complaints /Incidents
- User Feedback
- Investigator Initiated Studies (IIS)
- Literature Review
- Published Data from Regional or National Device Registries
- Expert Opinion

Real World Data

- **Patient Registries** (e.g. National Arthroplasty Registries)
  - National
  - Regional
  - Local, institutional
  - Manufacturers
- **Reimbursement and discharge data**
  - Data held by Health Insurances
  - Internal quality monitoring at public health institutions
- **Data generated by active medical devices**
- **Telemedicine** related to medical and diagnostic devices
  - Apps
  - Monitoring of diagnostic measures by physicians

Common understanding documents “Guidance Documents”

Current Status

Various Task Forces of the EU Commission are working on:

- Guidance on sampling of medical devices – **Published**
- Explanatory note on MDR codes – **Published**
- Guidance and templates for PSURs
- Guidance and template for SSCPs – **Published**
- Guidance on classification of Software as a Medical Device – **Published**
- Guidance and templates for PMCFs
- Guidance for sufficient clinical data
- Guidance for equivalence approach – Gap Document to MEDDEV 2.7.1 Rev. 4
- Common specifications, Clinical Evaluation Guidance for Software, etc.
- Implementing act for reprocessing single use medical devices

Thank you!