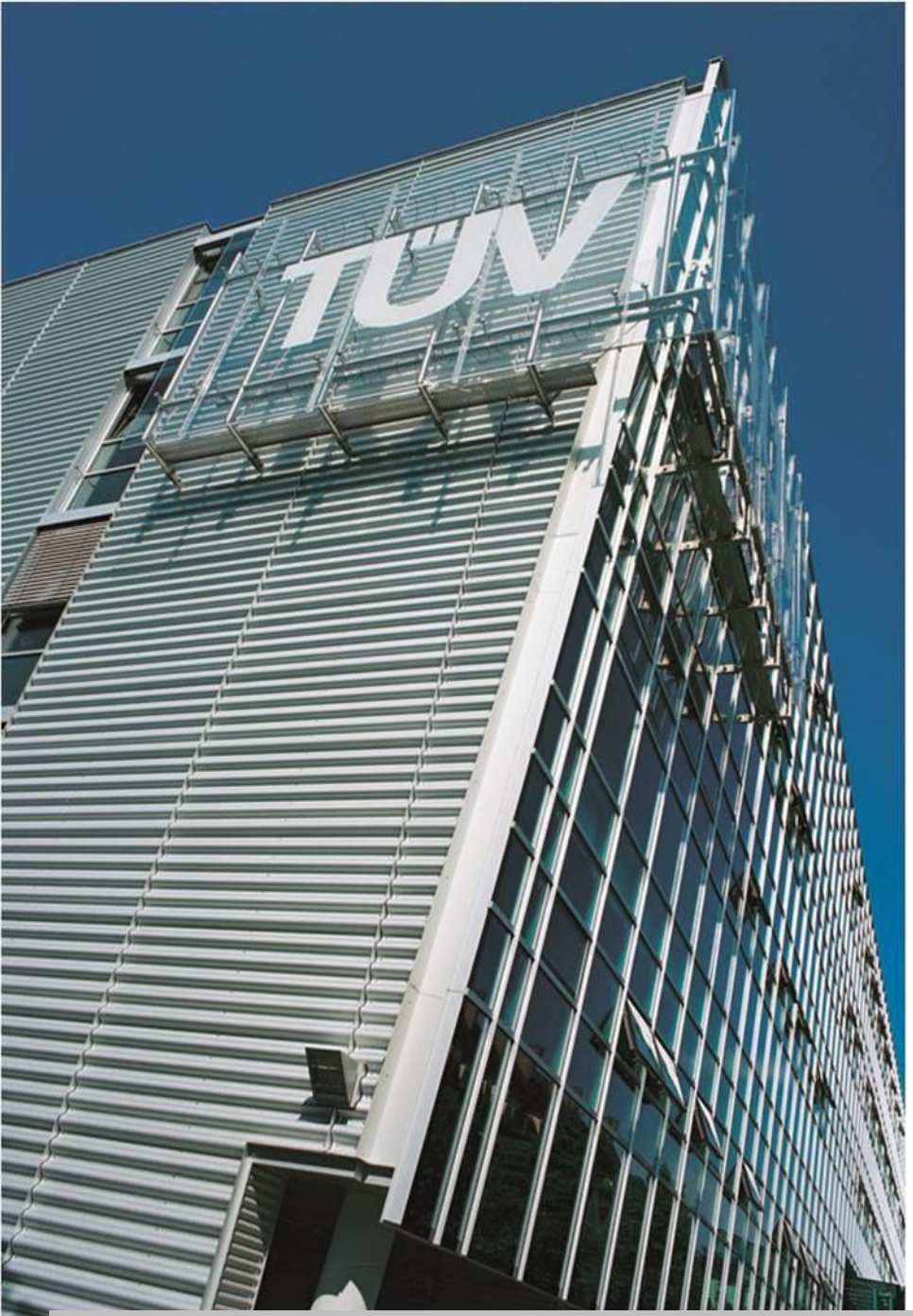


TÜV SÜD Product Service

Choose certainty. Add value.

Changing Roles of NB, Designation of NB, Impact of a reduced number of NB

TÜV Süd Product Service
Munich
Hans-Heiner Junker
International Affairs

Our Role

- After all discussions, meetings, controversial disputes: Europe will not introduce a EFDA
- Audit and certifying a quality management system and assessment of the medical device will still be in the hands of one body: the Notified Body
- However, for high-risk devices additional impact will be made by European expert panels and/or expert laboratories

Our roles

Audit & certify QMS according to regulations

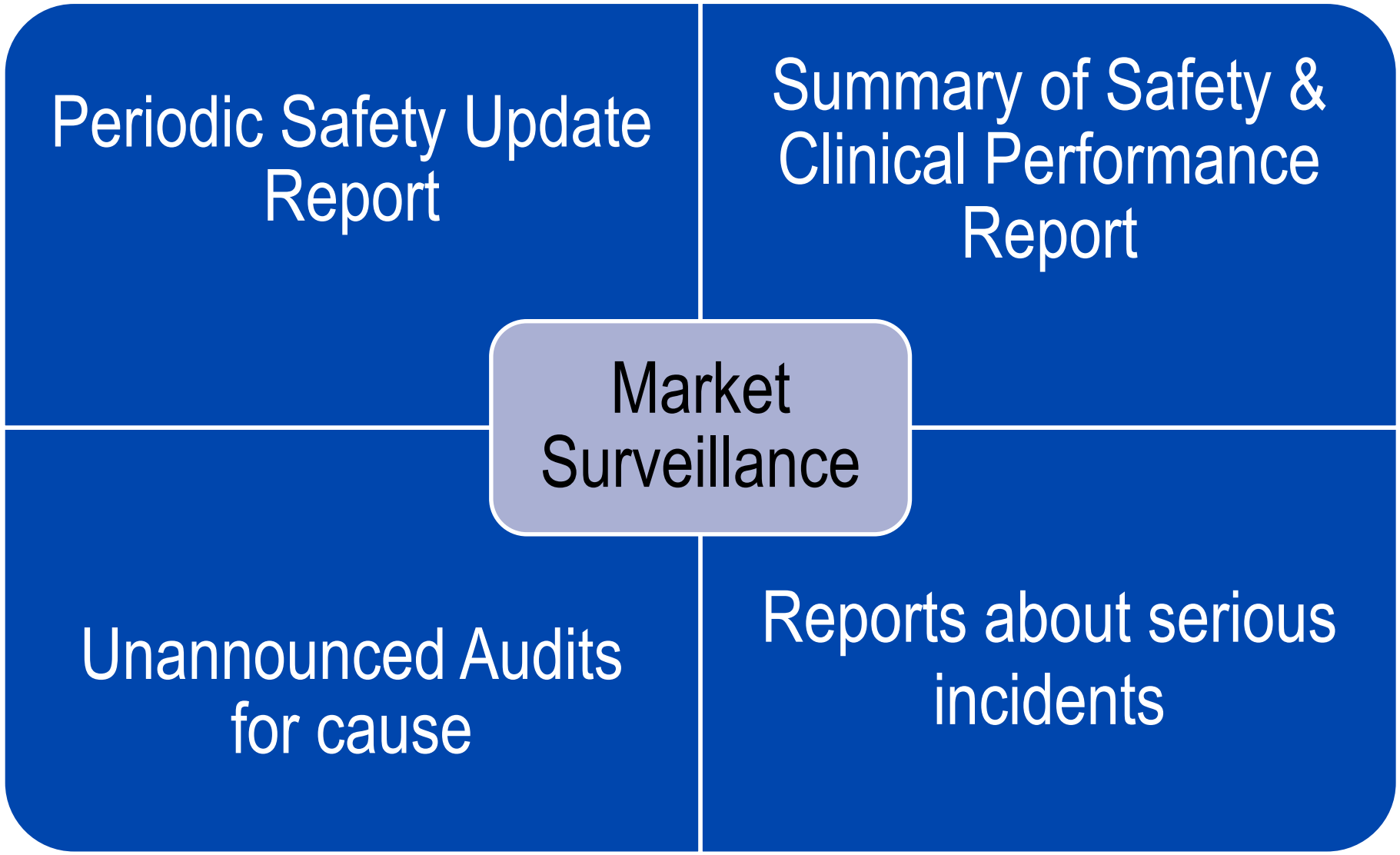
Assessment of medical devices (testing, TD reviews)

Notified Body

Unannounced Audits w/o cause

Increased responsibilites in the market surveillance

More Information from PMS



Additional Roles and Tasks

- Certification process of certain medical devices will need involvment of further authorities, like expert panel or reference labs
- More special procedures, like consultation on clinical evaluation
- Scrutiny Procedure

Designation Process; Principles

- Remember: one goal of the new MDR is to improve designation process and surveillance of Notified Bodies
- Joint Assessment Team will include special trained auditors
- Commission together with MDCG will appoint an audit team
- Team consists of:
  - At least three experts
    - One from the commission (coordinator)
    - One from two member states, different from the one responsible for the Notified Body
  - Audit team of the member state responsible for the Notified Body
  - Translators
  - Circumstances may require more
- For many steps of this process minimum working days are defined – all together more than 300 days, plus time needed for defining and accepting CAPA
- Designation process will use the NANDO database

General Designation Process

- Application to national authority from November 26, 2017
- In the course of this process, national authorities, the Commission, and the MDCG have to coordinate their activities
- Before designation is possible all member states have the right to raise objections
- Designation becomes valid one day after publication in NANDO
- Notified Bodies may perform activities of a notified body only after the designation has become valid.

Impact ! What Impact ?

- Nobody knows:
  - how many organizations will apply
  - who will apply at what time
- Some countries have only one applicant, others more
- Authorities explain duration:
  - average time between application and designation is 18 months
- But what will happen if some 50 organizations apply on one day in November 2017?
- Not all applicants will receive designation before the date of application of the MDR in May 2020, very unlikely
  - Most applicants will receive designation in 2019 or later
- Question: what tasks may an organization perform before official designation to shorten time after designation for the certification process?
  - How to be prepared for an audit by the „new“ Notified Body?
- Expect extremely busy Notified Bodies in the last 12 months of the transition time until May 2020

What to do ?

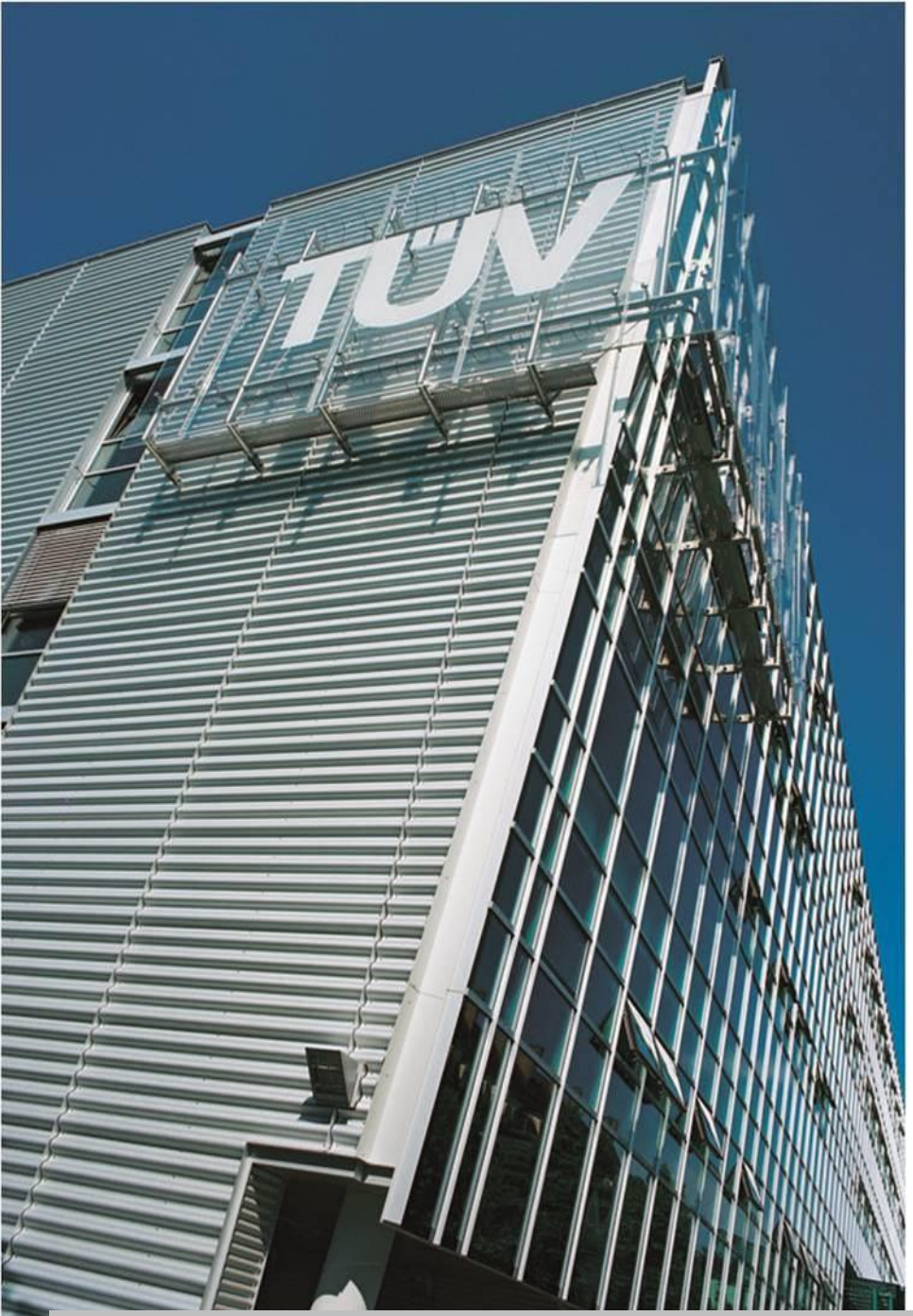
Close communication with Notified Body of choice

Prepare a transition plan, determine priorities

Analyze quality of your clinical data, now. Especially for implantable devices.

Strengthen your clinical procedures and competence

Be prepared to apply renewal of MDD/AIMD certificates in order to make use of the extended transition time until May 2024



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Thank you

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