PSDM
Pharmaceutische Statistiek en Data Management

"RISK-BASED APPROACHES"

Thursday the 25th of November
9.30 – 11.30 (CET)

PROGRAMME

9.30 **Welcome**

9.35 **RBQM in CDM – Getting ready for targeted querying?**
by Peter Stokman (business lead RAVEN, Clinical Data Management), Bayer, Berlin

10.05 **Risk-based statistical programming QC at Danone/Nutricia**
by Paul Vervuren (Principal Statistical Programmer) and
Gertjan van Maaren (Team Leader Statistical Programming), Danone, Utrecht

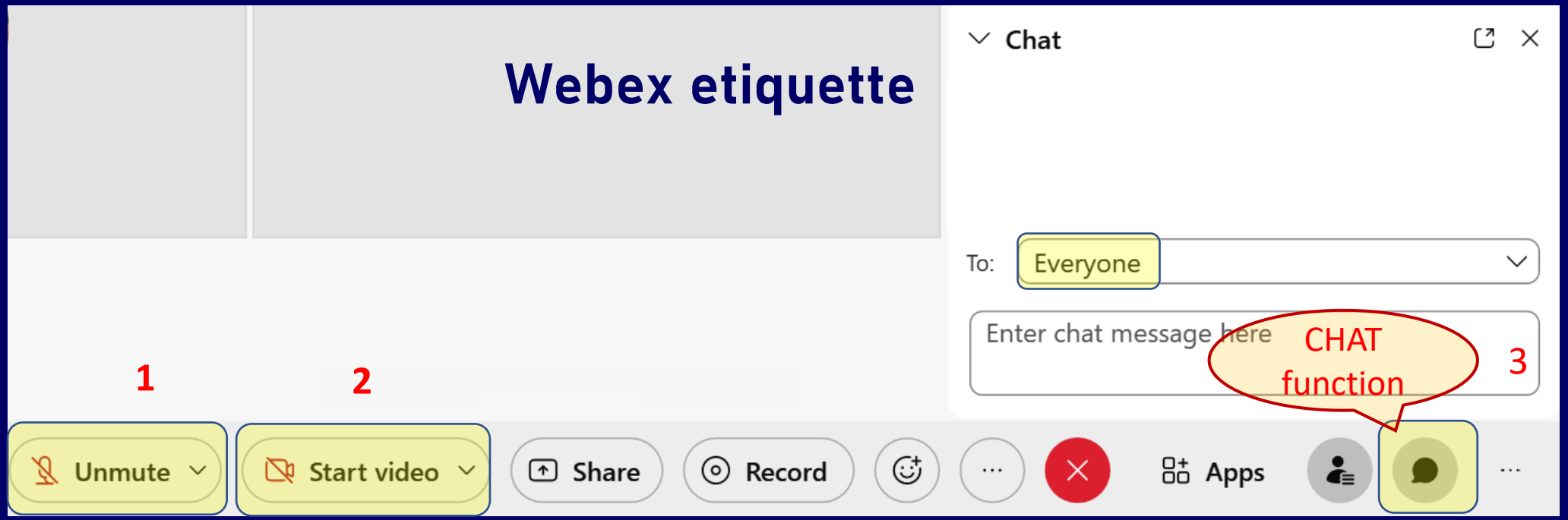
10.35 **Using central monitoring to detect data fabrication in multi-center clinical trials**
by Rutger van den Bor (assist. Prof. in Biostatistics, Julius Center) UMCU, Utrecht

11.00 Panel discussion with speakers

PSDM
Pharmaceutische Statistiek en Data Management

"RISK-BASED APPROACHES"

Thursday the 25th of November
9.30 – 11.30 (CET)



PSDM
Pharmaceutische Statistiek en Data Management

national network for professionals working in pharmaceutical statistics, programming and data management

- Working group of BMS of Dutch Society of Statistics (VVS) since 1993
- Board members

Egbert Biesheuvel
Chair, Portfolio Stats

Corine Baljé-Volkers
Secretary, Portfolio Stats

Alexander Adema
Portfolio Data Mng

Jules van der Zalm
Portfolio Programming

Frans Sollie
Treasurer, Portfolio Stats

“RISK-BASED APPROACHES”

INTRO

- Risk management principles common in areas where impossible to ensure quality of large volumes of services/products by exhaustingly checking accuracy of every item, like finance, insurance, public health, agrochemicals, manufacturing, etc

- **Quality risk management rather limited** in the area of GCP:
  - honest pursuit of highest quality for products that directly impact well-being of patients
  - re-GxP beginnings of pharma research based on use of paper CRFs
  - society is risk averse

- Led to practices that are extremely expensive and fail to deliver value justifying these costs Exhaustive manual verifications have shown their limits in identifying timely:
  - Issues related to protocol compliance
  - Safety related signals and trends across large datasets
  - Potential fraud

"RISK-BASED APPROACHES"

- Change in thinking by draft guidance documents in 2011:
  - **FDA - *Oversight of Clinical Investigations - A Risk-Based Approach to Monitoring***
  - **EMA - *Reflection paper on risk-based quality management in clinical trials***

- **Risk** refers to: *potential harm or the potential of an action/event to cause harm*

  Review of marketing submissions to FDA between 2000-2012, revealed 32% of all first-cycle review failures, or 16% of submissions overall, were driven by quality issues

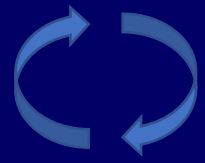
- **Quality**: degree to which a set of inherent properties of a product, system, or process fulfills requirements

“RISK-BASED APPROACHES”

Today, 3 presentations that discuss concrete examples and **applications of risk-based approaches within data management, statistical programming and statistics in the setting of clinical research.**

PROGRAMME

9.35 **Risk-based statistical programming QC at Danone/Nutricia**
by Paul Vervuren and Gertjan van Maaren



10.05 **RBQM in CDM – Getting ready for targeted querying?**
by Peter Stokman

10.35 **Using central monitoring to detect data fabrication in multi-center clinical trials**
by Rutger van den Bor