

Best Practices in a Remote Environment

Regulatory and Industry Perspectives on Remote Auditing

 Veeva MedTech

2021 © The MedTech Forum. All rights reserved - Reproduction in whole or in part is prohibited

2021 © The MedTech Forum. All rights reserved - Reproduction in whole or in part is prohibited

Today's Speakers

Panelists



Françoise Schlemmer

Director of Team-NB,
Team-NB



Alexey Shiryaev

President of Team-NB,
Team-NB



Andreas Purde

Director Active Medical
Devices, TÜV SÜD



Simon Richards

VP, Divisional Regulatory Affairs,
Abbott Rapid Diagnostics

Moderator



Annemien Pullen

Director of Strategy,
Veeva MedTech



The European Association Medical devices
Notified Bodies

MedTech Forum 2021

Remote/Virtual audits

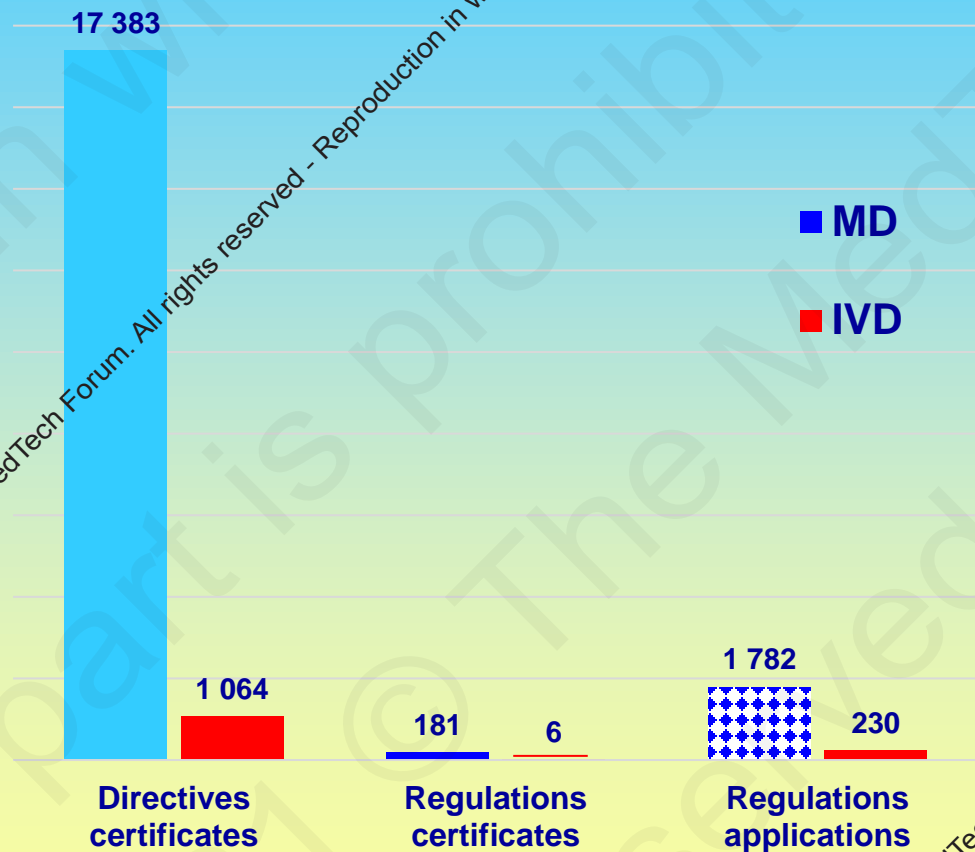
Françoise Schlemmer, Team NB Director

❖ Aims:

- **Communication with**
 - **European Commission**
 - **Competent Authorities**
 - **Industry**
- **Promote technical and ethical standards**
- **Participate in improving the legal framework**
- **Contribute to harmonization**
- **Represent Notified Bodies**



Certificates evolution



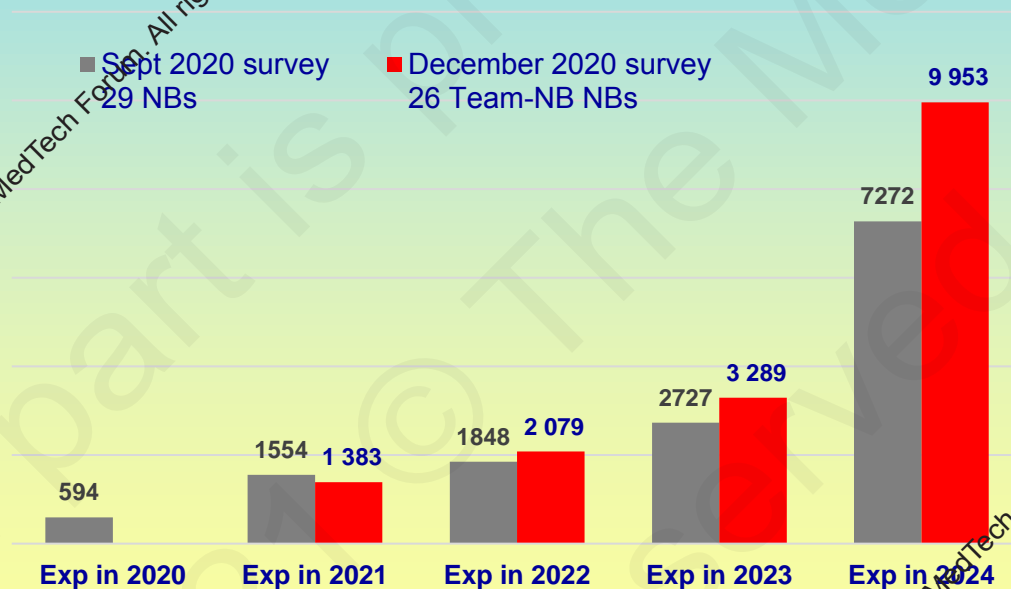
- 1% of MDR certificates has been issued.
- Applications represent 10% of MDD and AIMD certifications.

Expiration of directives certificates

■ Sources:

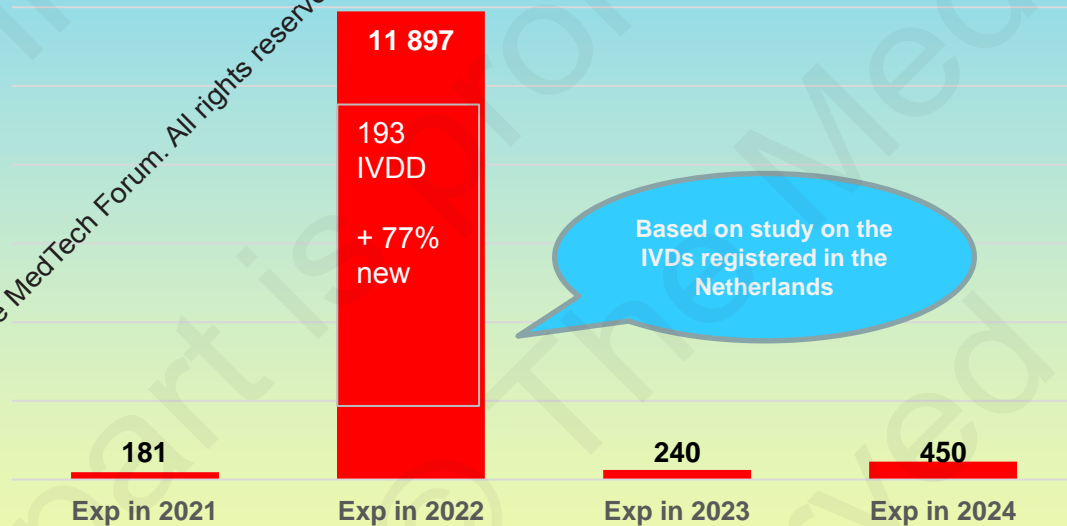
- September survey: CIRCABC with 29 responses – all NBs
- December survey: All Team-NB members – 26 responses

Expiring AIMD + MDD certificates



- MDD / AIMD certificates against directives increased thanks to the remote audits authorised by the Commission

IVD: expiration of directives certificates & new IVDR requests



- IVDD certificates = only small part
- Part of the devices requesting certificate against the IVDR more important (estimation thanks to study made in 2018 on the IVDs registered in the Netherlands)

Remote Audit Survey : Analysis

❖ Source EUSurvey

- all Medical Devices Notified Bodies (n=54) received on September 28th, 2020, an invitation to the survey 'Notified Body Experience with Remote Auditing'
- The survey was closed on October 29th with 37 responses from Notified Bodies.

❖ Number of remote audit days

- 12 860 against the directives and
- 389 days against the regulations for Covid-19 clinically necessary products or partial audits.

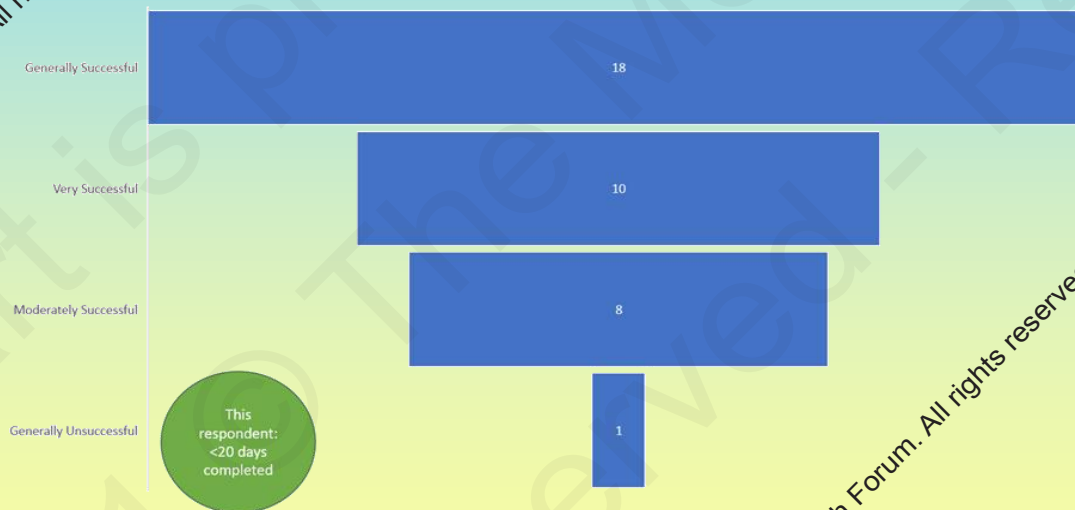
→ **These significant numbers of auditing days can allow us to consider the results as revealing.**

Remote Audit Survey : Analysis

❖ **75% of these audits has been considered successful or very successful.**



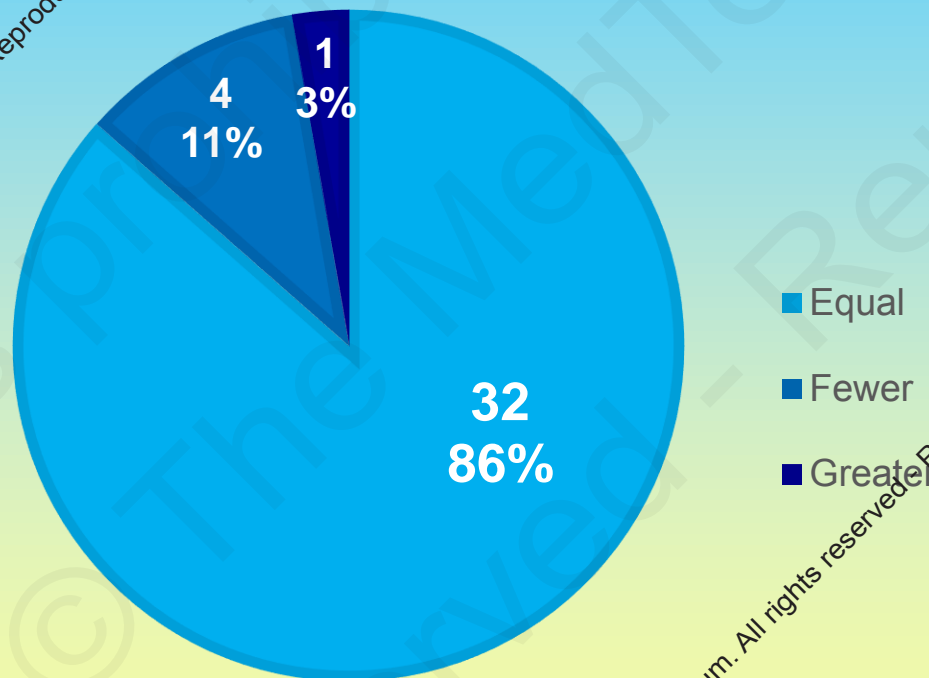
What is your experience with remote audits?



Remote Audit Survey : Analysis



Number of raised non-conformities



⇒ **86% of the notified bodies issued an equal number of non-conformities.**

Remote Audit Survey : Analysis

- ❖ **These remote audits have allowed auditors to perform all necessary audit tasks:**
 - **interview operators of equipment**
 - **interview document and record owners**
 - **review documents**
 - **video camera view of records, equipment, manufacturing areas**

... not different from on-site tasks.
- ❖ **Ten different NBs witnessed by authorities.**
- ❖ **Remote audits allowed transparency**
- ❖ **Positive feedback is great majority.**

Contacts



Management:

- ◆ **Alexey Shiryaev** (Alexey.Shiryaev@dnvgl.com) – president
- ◆ **Guy Buijzen** (guy.buijzen@dekra.com) – treasurer
- ◆ **Gero Viola** (gero.viola@de.tuv.com) – secretary
- ◆ **Suzanne Halliday** (Suzanne.Halliday@bsigroup.com) – vice president
- ◆ **Sabina Hoekstra-van den Bosch** (Sabina.Hoekstra@tuv-sud.nl) – vice president
- ◆ **Françoise Schlemmer** (schlemmer@team-nb.org) -Director and Secretariat

www.team-nb.org





Members



ΕΘΝΙΚΟ ΚΕΝΤΡΟ ΑΞΙΟΛΟΓΗΣΗΣ
ΤΗΣ ΠΟΙΟΤΗΤΑΣ & ΤΕΧΝΟΛΟΓΙΑΣ
ΣΤΗΝ ΥΓΕΙΑ Α.Ε.
NATIONAL EVALUATION CENTER
OF QUALITY & TECHNOLOGY
IN HEALTH S.A.

