The European Association Medical devices
Notified Bodies

CIRCABC Remote Audit Analysis

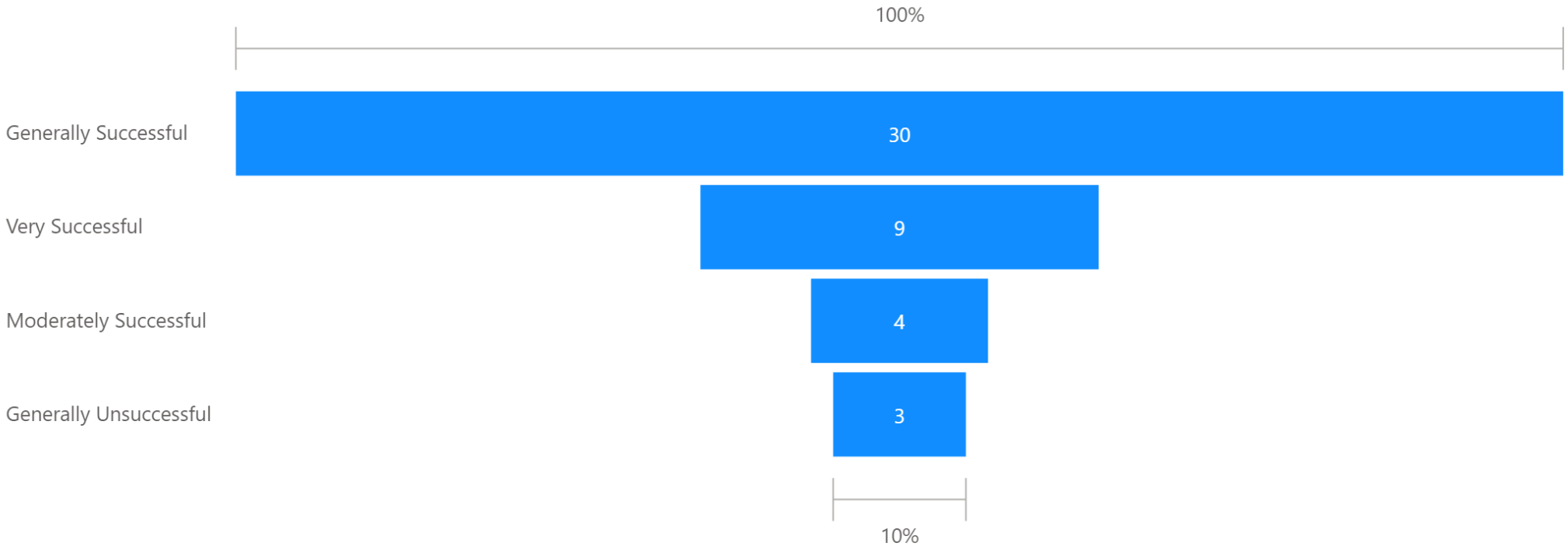
May 2021

Remote Audits Analysis

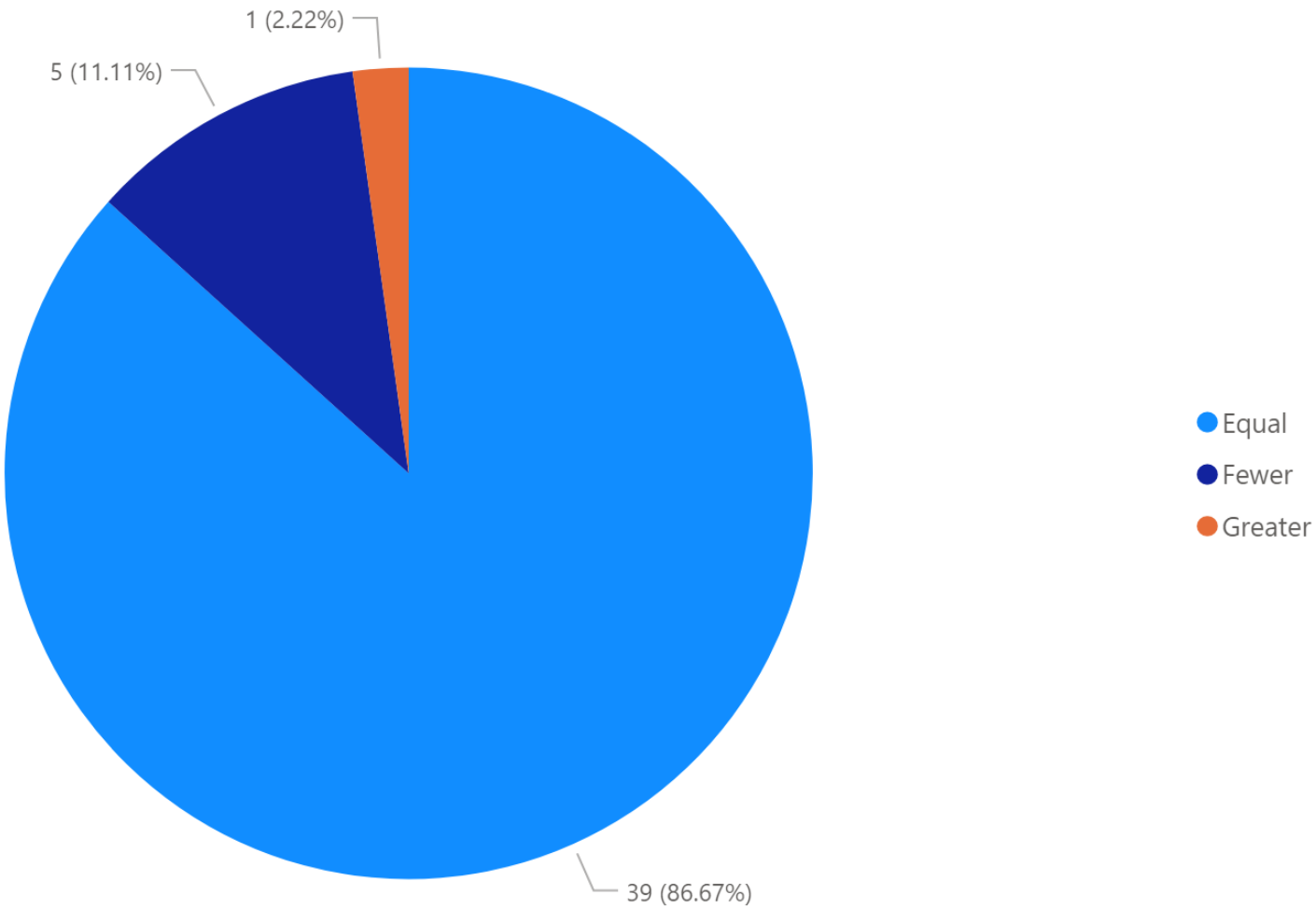
- Thanks to EUSurvey, the European Commission's tool
- Sent to all designated NBs (52) in the CIRCABC database
- Number of answers = 46 (i.e. 88%)
- Numbers of auditing days (> 33 000 days)

→ consider these results as revealing.

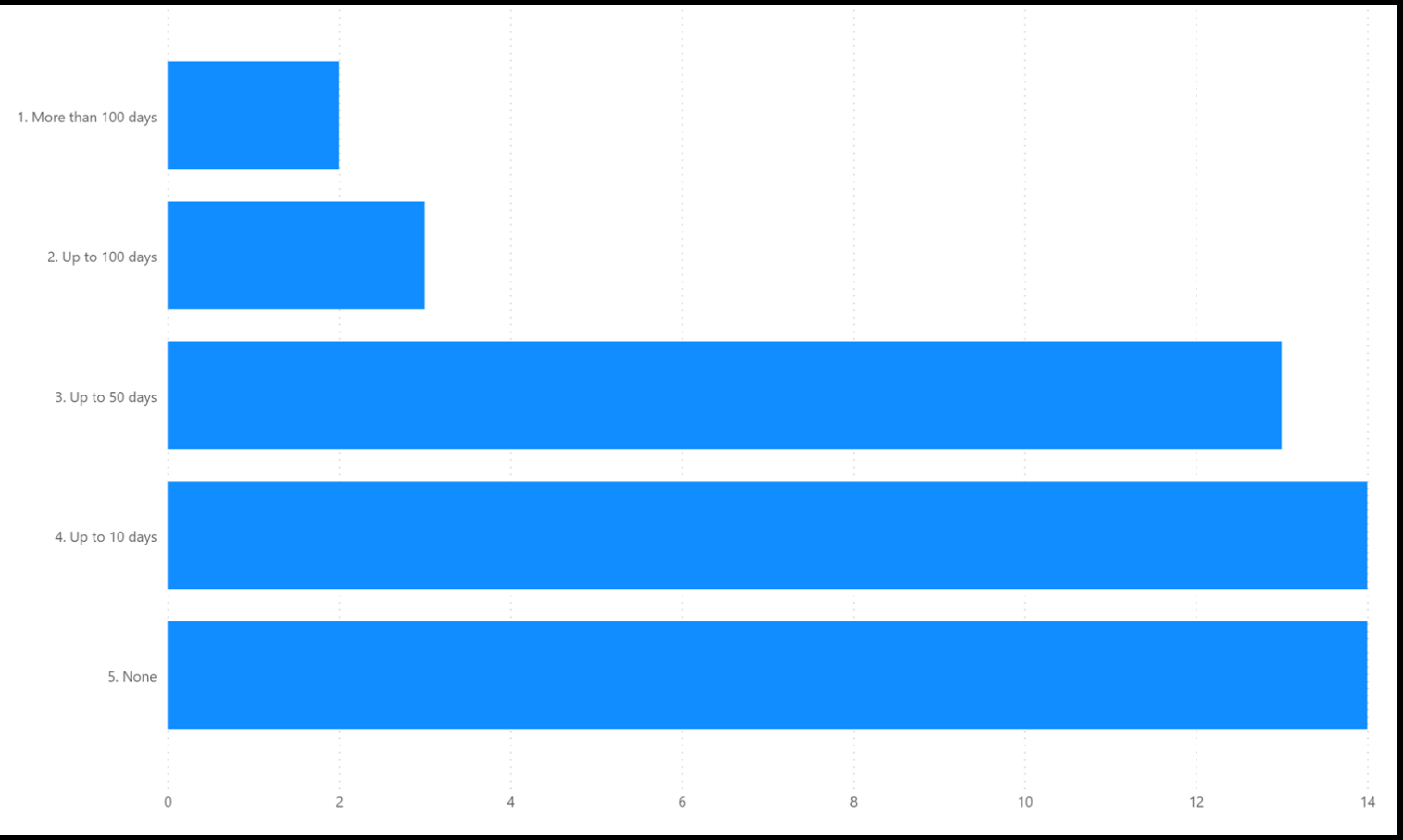
What is your experience with remote audits?



On average, did your NB raise more or less or equivalent number of non-conformities in remote audits compared to onsite audits?



How many audit days have been completed remotely for 'clinically necessary devices?



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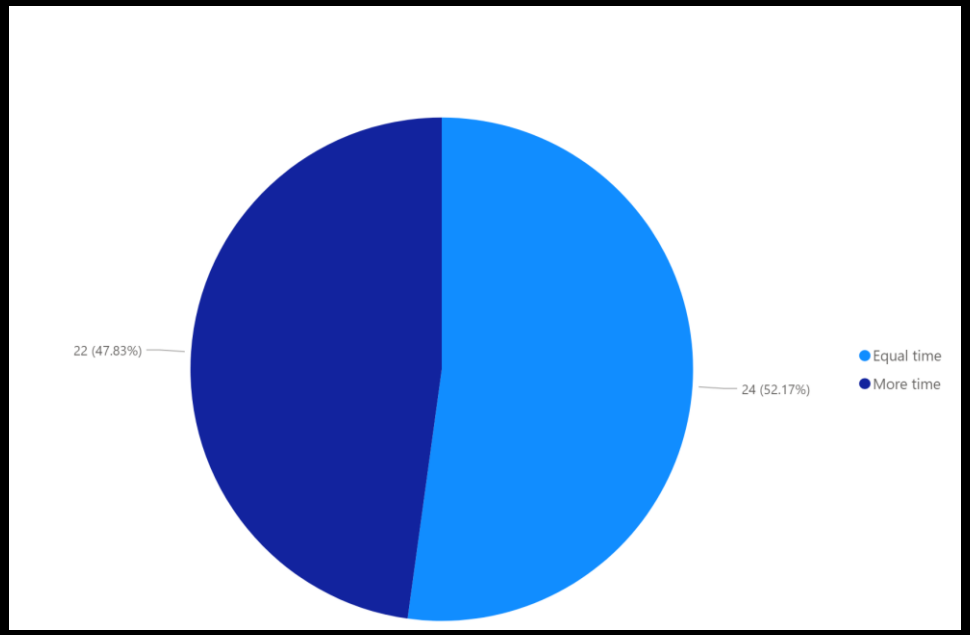
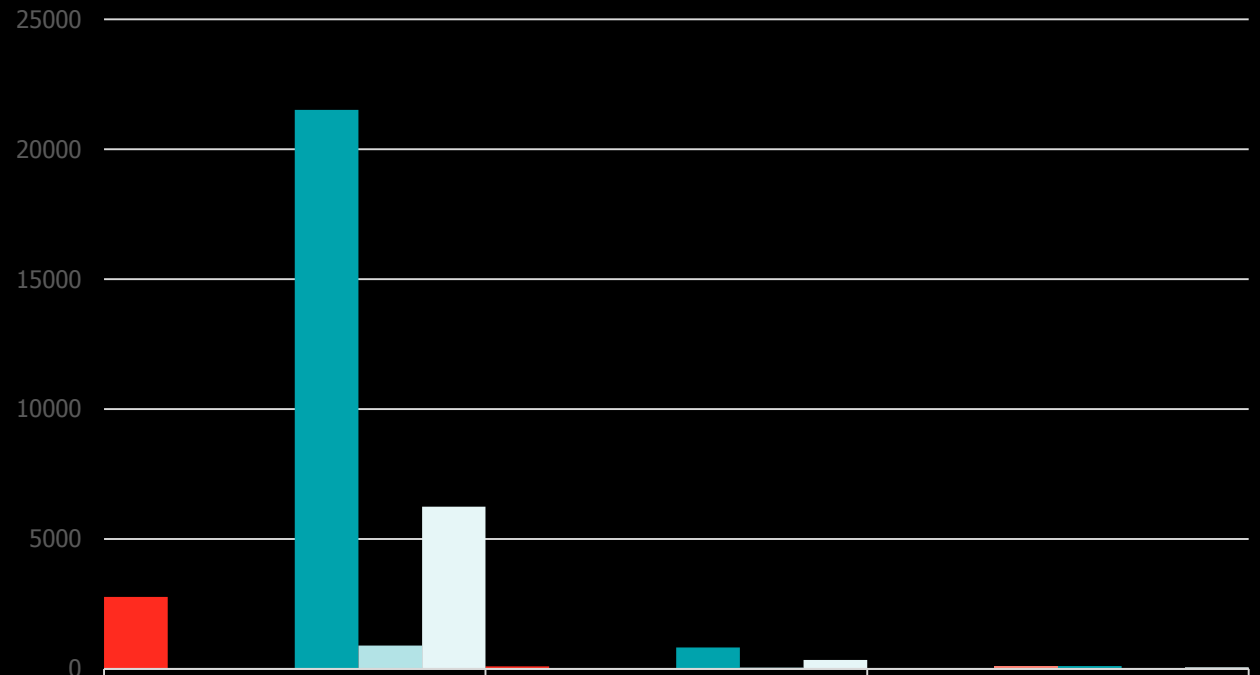


1/3 – 1 2/3 more days
5% - 33% more of the audit time

Number of Remote Audit Days by Type

Directives
32,729



	AIMDD/MDD/IVDD - Legal Manufacturers	AIMDD/MDD/IVDD - Suppliers / Subcontractors	MDR/IVDR - Legal Manufacturers
Initial	2769,2	98	
Initial - 'clinically necessary'			35
Initial - 'partially remote'			108
Surveillance	21511,1	818,1	112
Extension to Scope	896	50	22
Re-assessment	6244,7	343	60

Regulations
337

Sharing Experiences

Successful

- Decreases travel time and cost
- Tight focus
- Easier to take notes
- Very effective for non physical processes (like software) and pure QMS aspects
- The verification of the quality of records is more accurate than in an onsite audit
- Remote audits are more successful with established customers

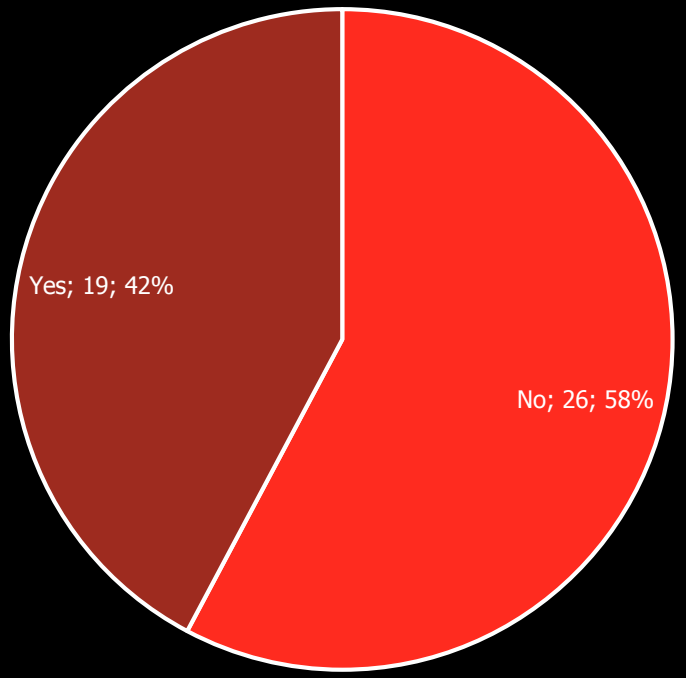
Unsuccessful

- Issues when there is a large time difference
- Issues with internet connections
- Video does not permit to see and look for as if we were onsite
- Generally, the spontaneousness of auditing, i.e. reacting immediately to an issue/sample picking

Are there particular clauses of MDR/IVDR related to audits that you think cannot be completed remotely?

- Infrastructure [ISO 13485 - §6.3]
- Work environment and contamination control [ISO 13485 - §6.4]
- Production and service provision [ISO 13485 - §7.5]
- Sampling for control of monitoring and measuring equipment [ISO 13485 - §7.6]
- Handling of nonconforming products [ISO 13485 - §8.3]
- MDR Clauses that must be audited on-site: 10.1, 10.9(g), 10.9(k), and 10.9(m)
- Cleanroom
- Physical devices (manufacturing process)
- For Surveillance a deeper look into production is needed, which is limited remotely
- Production
- MDR, Annex VII, 4.5.2 b)
- MDR Annex IX, Point 2.3, 3.3, however, Commission Notice C/2021/119 applies.

Have any of your remote audits been witnessed by an accreditation body, designating authority or other regulatory body?



- Auditors have been praised for good preparation and time keeping.
- Commented that there might be more time needed to be added to the usual calculated audit time.
- The remote nature of the audit did allow for multiple regulatory personnel to be present, which did feel a little like the witnessed auditor had 3 times the scrutiny, though.
- The observers' presence seems to be less noticeable and therefore less intimidating to the audit team and the auditee
- The only noticed downside is the reduced opportunity for the observers to discuss the audit process with the audit team in a remote setting, resulting in a need to provide additional written explanations of the process after the witnessed audit, or a need of additional virtual meeting with the authority.