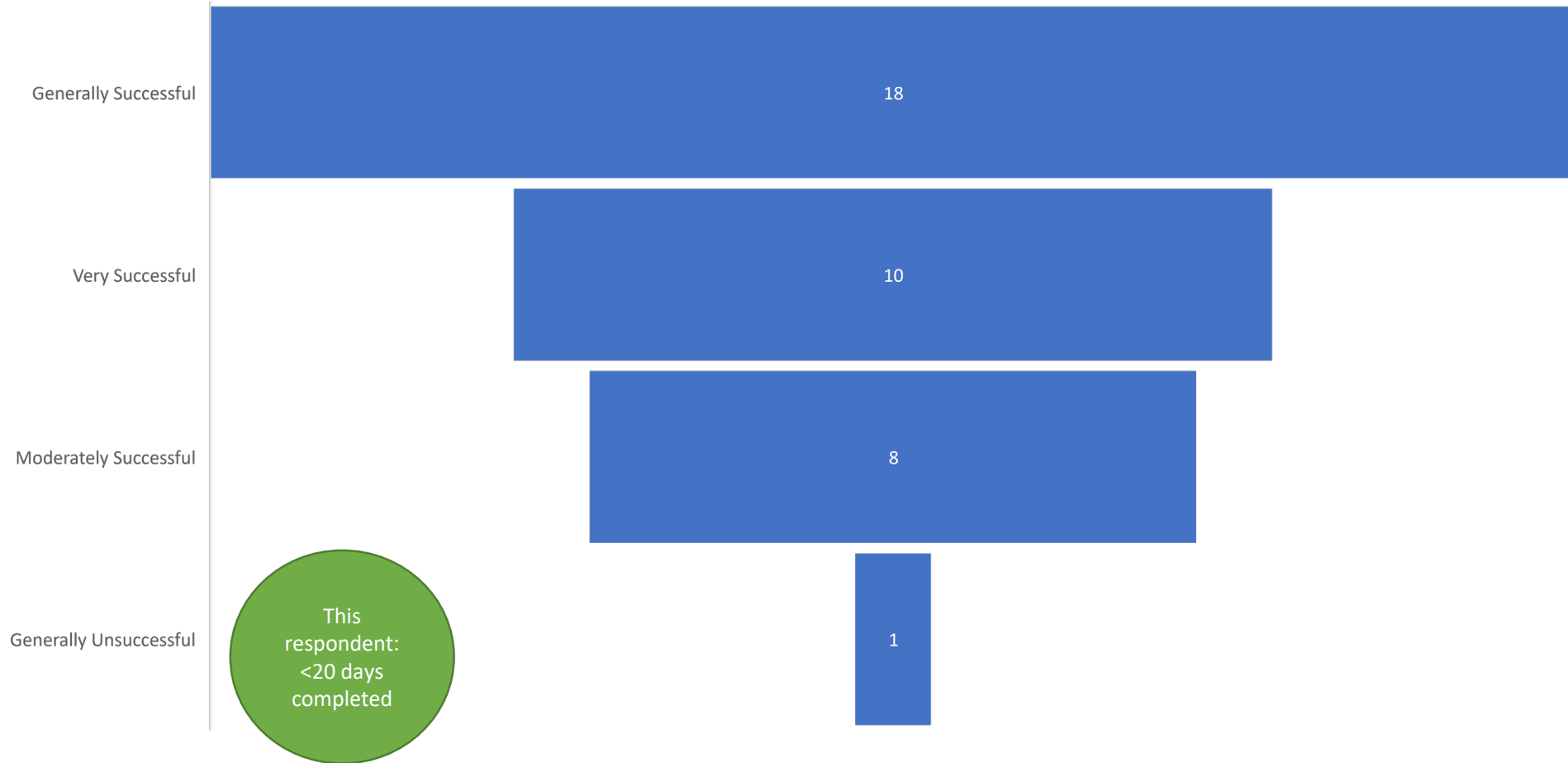


Remote Audit Survey Analysis

October 2020

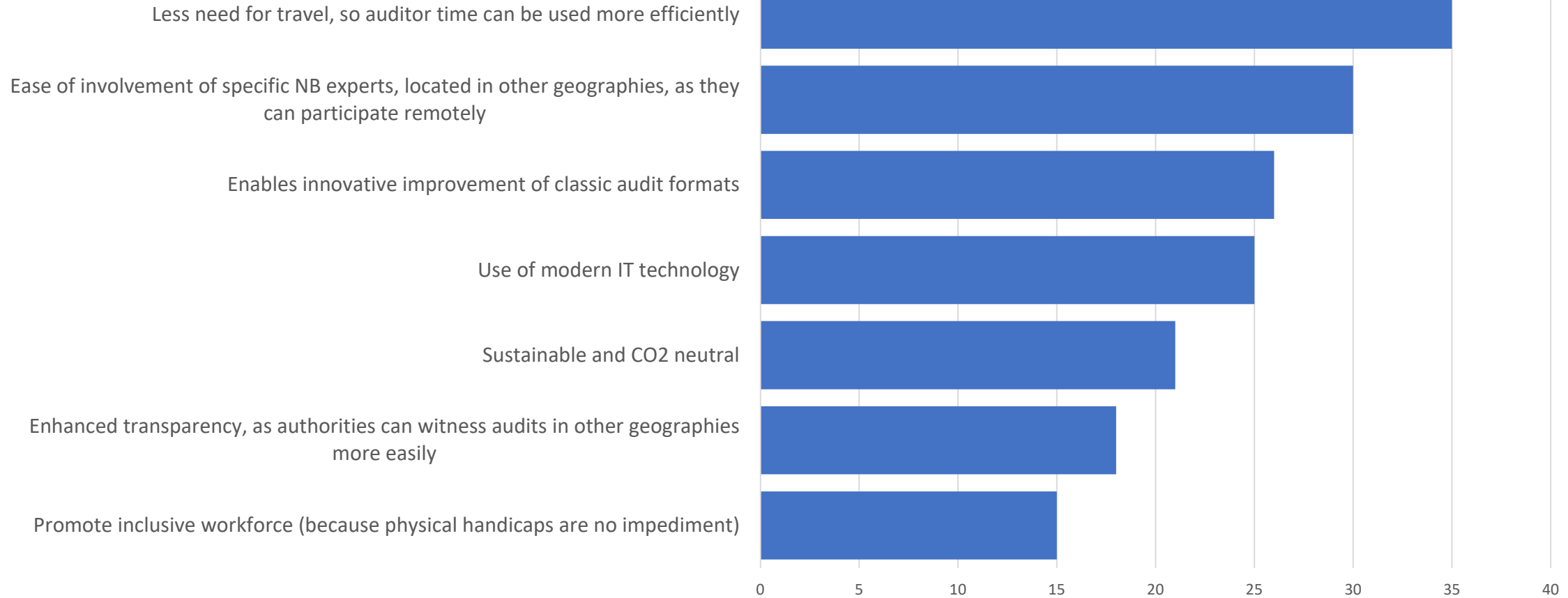


What is your experience with remote audits?

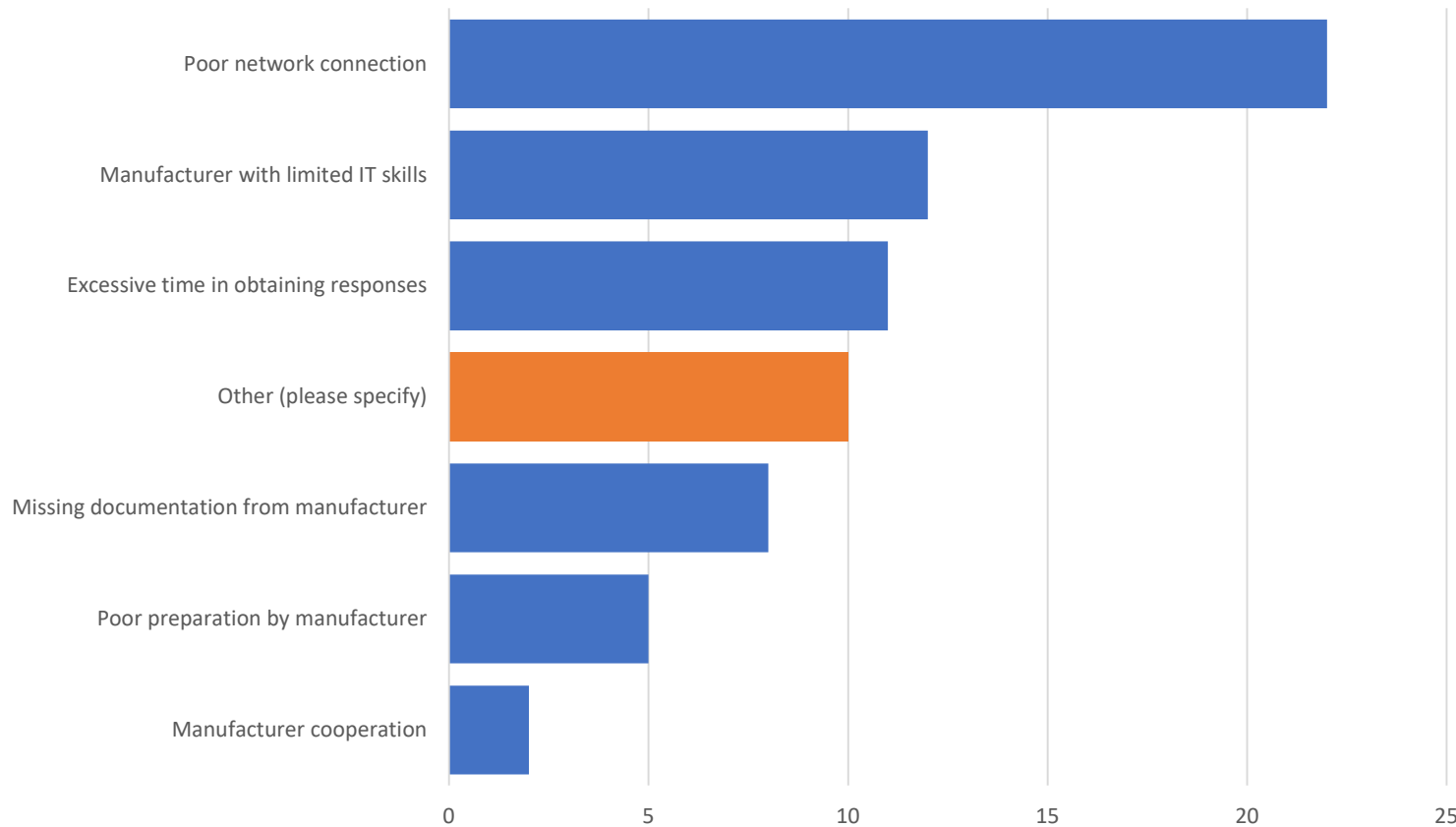




What do you consider as positive aspects of remote auditing?



What are the most common issues / obstacles that you have encountered with remote audits?

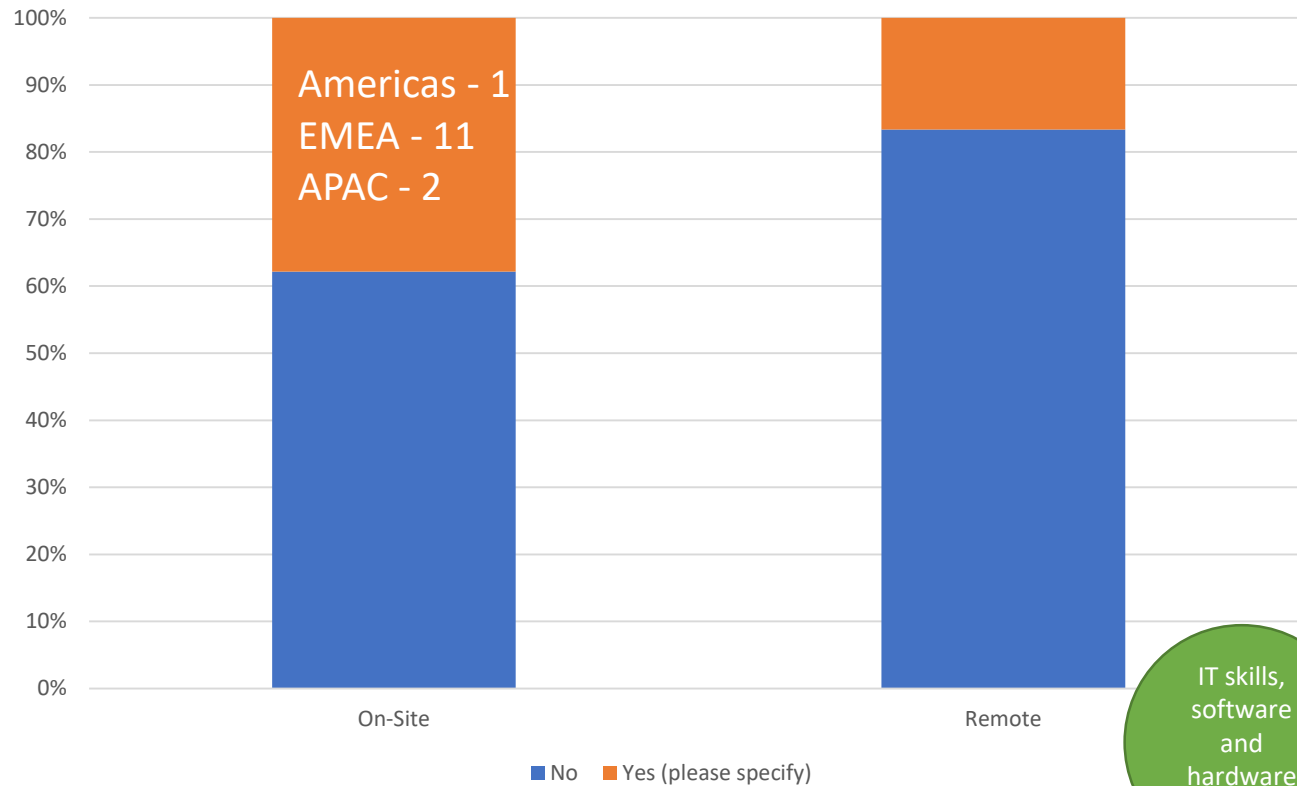


Other:

- Issues with image and sound
- Paper records
 - Not clear when shown on camera
 - Review of production documentation lengthy because documents had to be scanned/ digitalized
- Time difference
- More superficial image of company

Obstacles improving over time

Have there been instances that your auditors were denied access to a site?

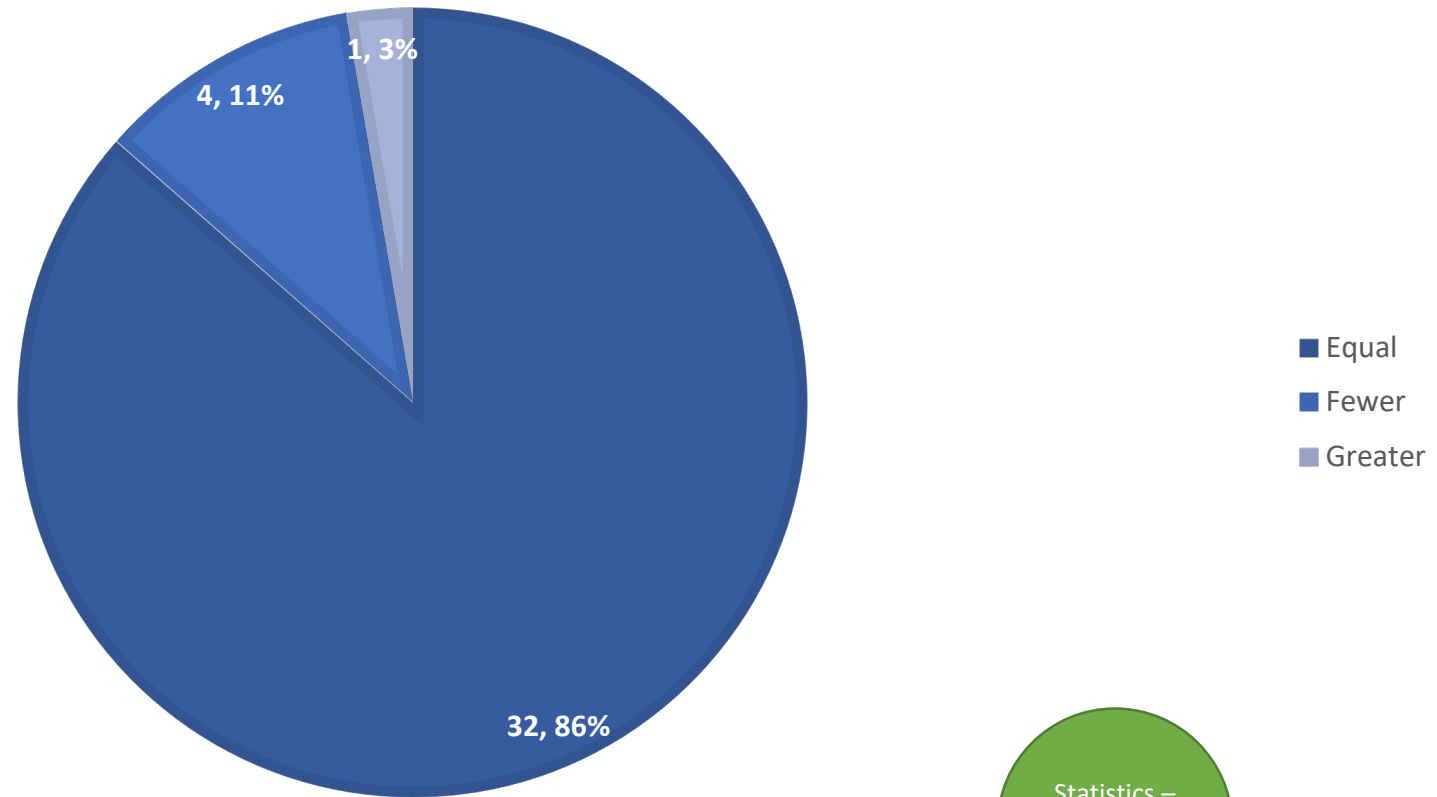


IT skills, software and hardware improving

Reasons for denied access to site:

- Lack of resources onsite (due to staff access restrictions)
- Separation measures for staff in order to avoid infection
- Staff in risk groups (e.g. age >60)
- No staff available at all
- Infection risk to production staff for critical devices
- Site closure
- Site in high risk area
- Auditor coming from high risk area
- Too busy with COVID-response (production, e.g. masks, ventilators; patientcare e.g. NHS-hospital)
- Manufacturer cannot afford audit due to COVID-related financial loss

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

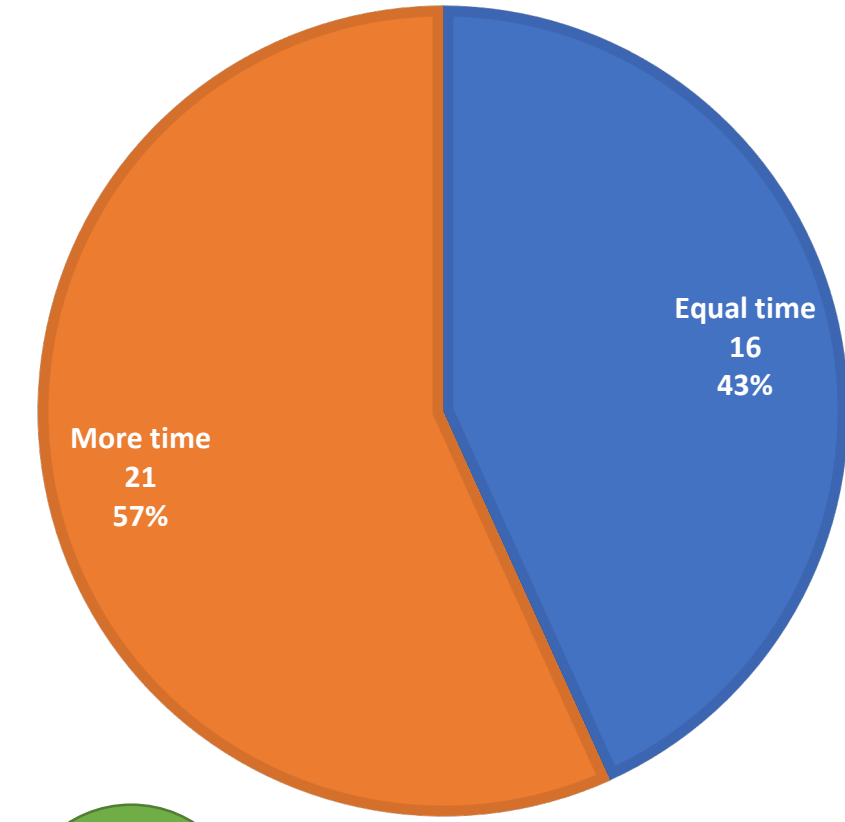
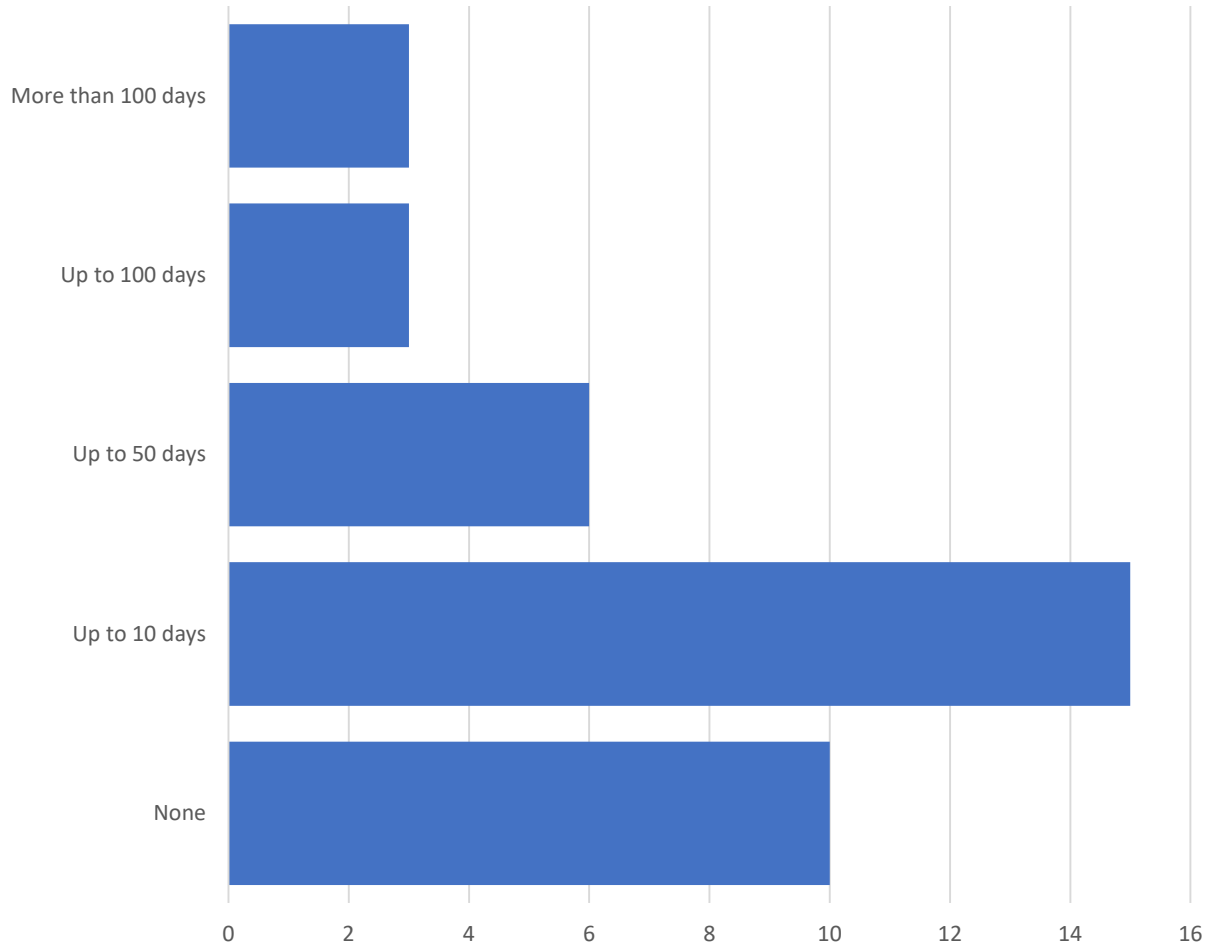


Statistics –
Mann
Whitney



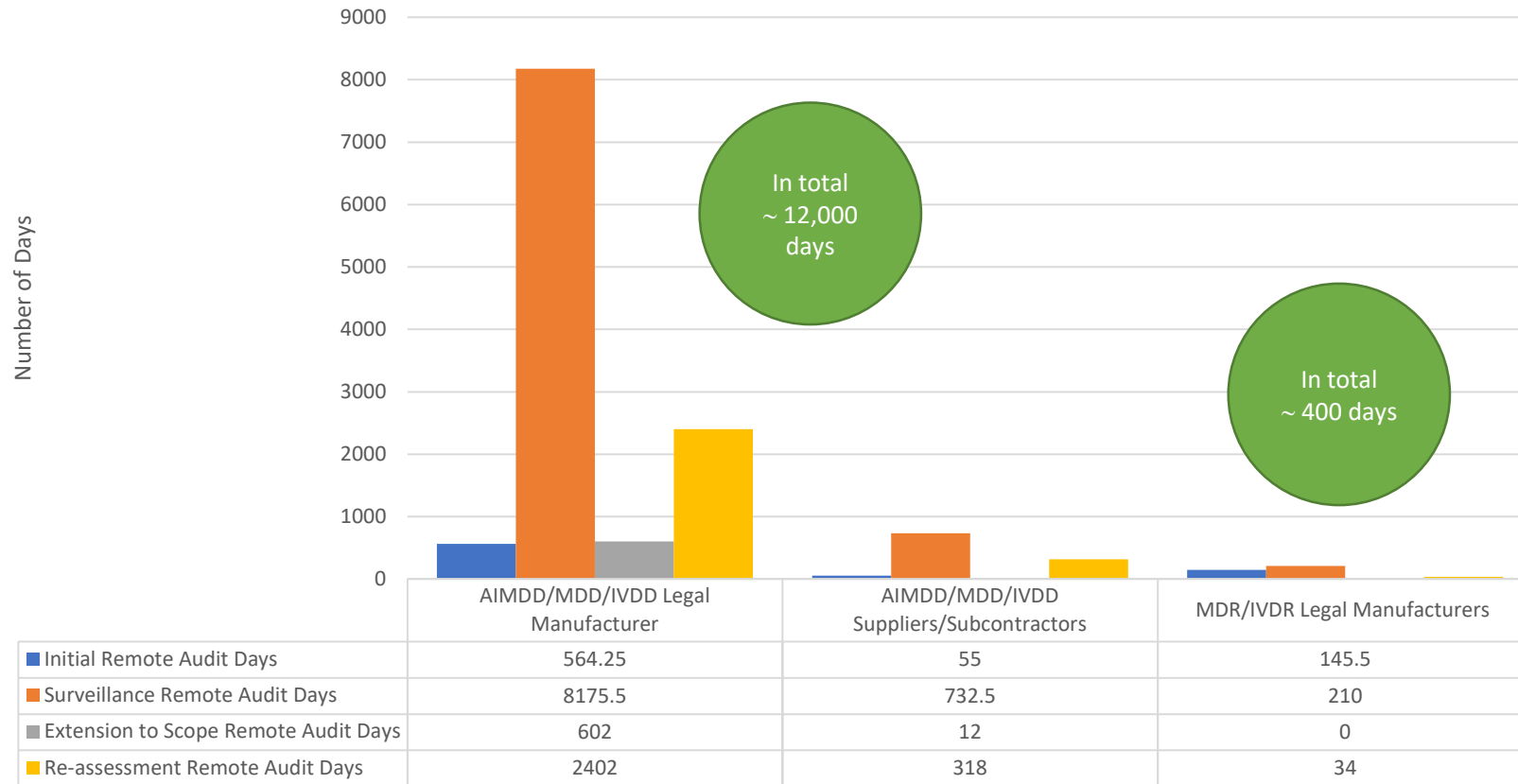
How many audit days have been completed remotely for 'clinically necessary devices?' (See MDCG 2020 4 - 'clinically necessary' are devices for patients with CoVid19)

In your experience, for the same audit agenda, did you need more time or less time to complete the audit remotely compared to an onsite audit?

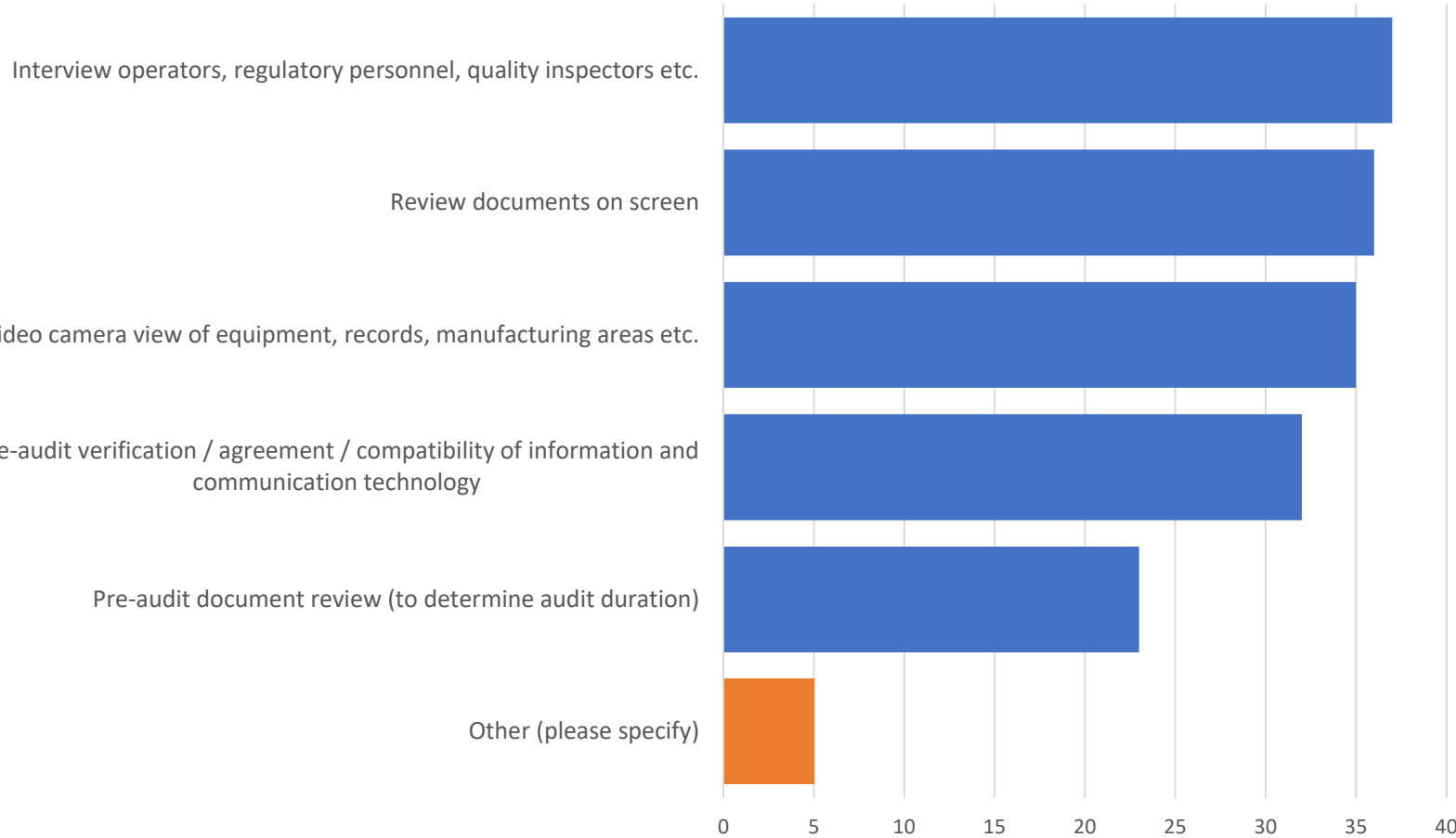


½ - 2 more days
10-20% more time

Number of Remote Audit Days by Type



What have your auditors been doing during remote audits?

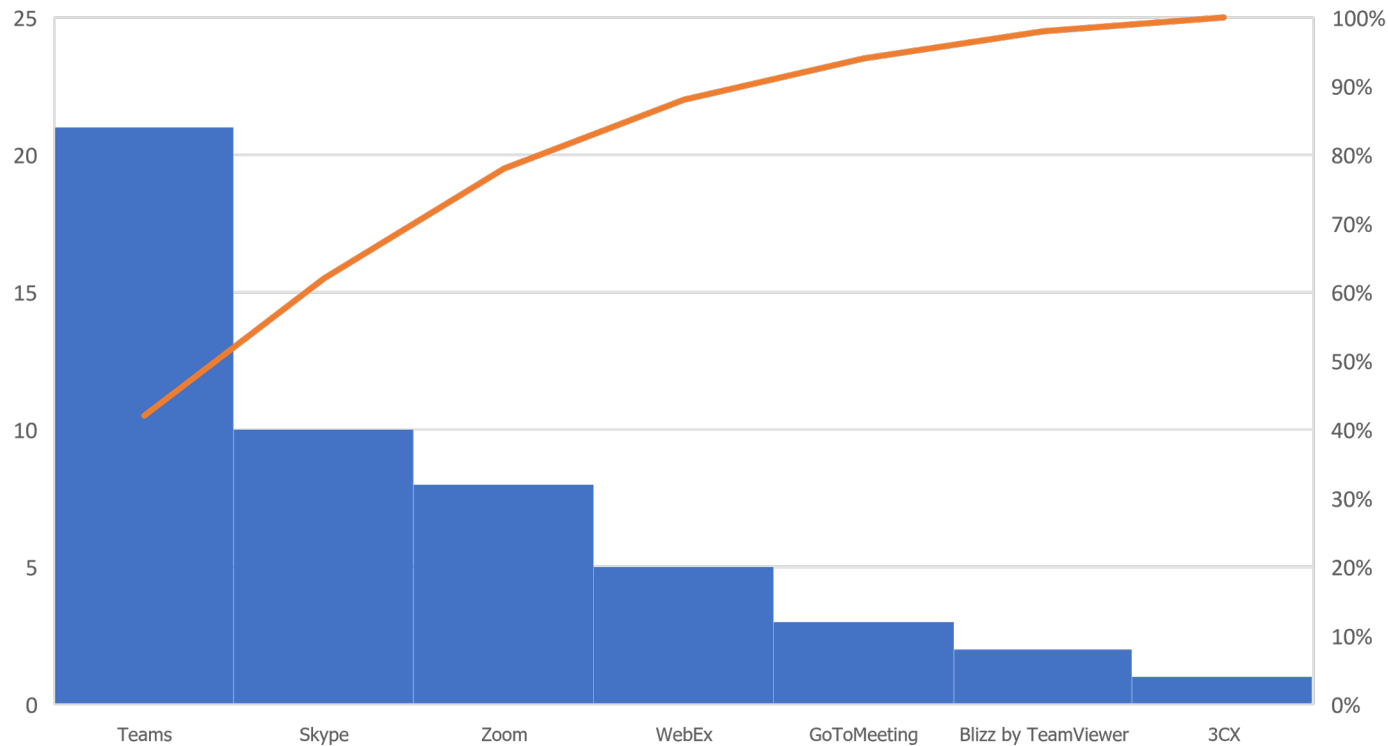


Other:

- Inspection of software development, process and source code reviews
- Review all available information:
 - audit last report
 - technical documentation of medical devices included under the scope
- Document review off-site during the audit
 - review of submitted documentation
- Request to send the records and evidence of the QS and regulatory aspects before remote audit



What method of communication have you been using to complete remote audits?



- Many people have used multiple platforms
- Depends on the choice/ability of the manufacturer or subcontractor being audited