



Global Medical
Technology Alliance
Innovating for a Healthier World

Remote Audits

IMDRF Stakeholders Session
March 23, 2021



Global Medical
Technology Alliance
Innovating for a Healthier World

Outline

- Background
- Remote Audits
 - Basic Principles
 - Recommendations



Background

- Regulators have adopted a number of agile, safe and pragmatic regulatory policies to help address the global public health emergency
- Given the safety concerns and travel restrictions, some regulators are doing remote audits
 - MDSAP accommodates for remote audits
 - European Commission recognizes the need
 - US FDA is conducting a pilot
 - ISO foresees remote audits as an acceptable auditing method
 - Already embraced in other sectors (e.g., pharma)

3

References:

- International:
 - ISO 9001 Auditing Practices Group – Guidance on remote audits
 - ISO 19011:2018 Guidelines for Auditing Management Systems
 - [MDSAP Transmittal Number](#): AO 2020-10 [Superseding MDSAP Transmittal Number 2020-07]; Transmittal Date: 2020/12/31
Title: Further Extension and Expansion of Temporary Extraordinary Measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – alternative audit arrangements
- Europe:
 - [MDCG 2020-4](#) *Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions*, April 2020
 - [MDCG 2020-17](#) Questions and Answers related to MDCG 2020-4, December 2020
 - [Commission Notice](#) on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment (Text with EEA relevance) 2021/C 8/01; C/2021/119



Remote Audit

- Remote Audit is an audit performed off-site using information and communication technology.
 - It mirrors all the activities that are carried out during an on-site inspection and may include, for example:
 - Remote records review
 - Real-time virtual interaction using technology
- A robust alternative to physical inspection
 - Experience with remote audits so far has demonstrated an adequate level of safety with no compromise to the overall reliability of assessments

4

References:

- [MDSAP Transmittal Number](#): AO 2020-10 [Superseding MDSAP Transmittal Number 2020-07]; Transmittal Date: 2020/12/31

Title: Further Extension and Expansion of Temporary Extraordinary Measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – alternative audit arrangements

- [Commission Notice](#) on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment (Text with EEA relevance) 2021/C 8/01; C/2021/119



Global Medical
Technology Alliance
Innovating for a Healthier World

Remote Audit

- Optimizing regulator, conformity assessment bodies and industry human and financial resources (e.g., cost, quality and delivery means) as well as other benefits, such as minimizing the environmental footprint, speed of use and a quick execution of required inspections.
- Remote Audits are currently being used by industry and will be expanded over the coming months to include supplier audits, ethics and compliance audits and intercompany audits.

5

References:

- [MDSAP Transmittal Number](#): AO 2020-10 [Superseding MDSAP Transmittal Number 2020-07]; Transmittal Date: 2020/12/31

Title: Further Extension and Expansion of Temporary Extraordinary Measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – alternative audit arrangements

- [Commission Notice](#) on the application of Sections 2.3 and 3.3 of Annex IX to Regulation (EU) 2017/745 and Regulation (EU) 2017/746 with regard to notified bodies' audits performed in the context of quality management system assessment (Text with EEA relevance) 2021/C 8/01; C/2021/119



Basic Principles

- Use available technology
- Replacement for physical inspection
- Same or similar scope as physical inspection
- Should be included as an overall part of audit plan that also includes recognition and reliance of existing audits (e.g., MDSAP)
- A lesson learned from the COVID-19 pandemic – Remote audits are beneficial during a public health emergency



Recommendations

- GMTA supports further development of concepts and principles for remote audits
- GMTA encourages regulators to consider the use of remote audits as a viable alternative to physical inspections (on-site audits) under specified circumstances



Global Medical
Technology Alliance
Innovating for a Healthier World

Early Lessons Learned During a Global Pandemic

IMDRF Stakeholders Session

March 23, 2021



Presentation Outline

- Background
- Challenge
- Early Lessons Learned
- Recommendations



Background

- Need for rapid review and approval mechanisms to meet specific needs during COVID-19 pandemic
- Access to COVID diagnostic tests, personal protective equipment, ventilators in high demand
- Required close collaboration with regulators, developers and healthcare providers



Challenge

- Clinical and Regulatory
 - Access to virus samples
 - Accuracy of, and access to, comparator test
 - Changing and moving targets
 - Lack of clarity in regulation
 - Lack of harmonization in regulations to enable marketing authority at pace with urgent need to scale
- Scaling production in a short period of time
- Access to Real World Data



Early Lessons Learned

- Leverage regulatory decisions from other regulators
- Regulatory agility during pandemic has been critical
 - Remote audits in place of on-site
 - Leverage regulatory reliance
 - Use of alternative sources for clinical evidence



Recommendations

- Ensure that current IMDRF documents acknowledge the need to ensure rapid review and approval
- Utilize reliance mechanisms to promote rapid review and approval
- Consider the development of specific IMDRF guidance to promote the use of rapid review and approval mechanisms during a global pandemic
- Ensure adequate training and communication for regulators
- Regulatory agility should be leveraged beyond pandemic