

# ISO/TR 20416:2020 (E)

## Medical devices — Post-market surveillance for manufacturers

---

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Purpose of post-market surveillance process
5	Planning of post-market surveillance
5.1	General
5.2	Scope of the post-market surveillance plan
5.3	Objective of the post-market surveillance plan
5.4	Responsibilities and authorities
5.5	Data collection
5.5.1	Data sources
5.5.2	Defining data collection methods
5.5.3	Developing the data collection protocol
5.6	Data analysis
5.6.1	General
5.6.2	Considerations concerning planning the data analysis
5.6.3	Methods for data analysis
5.7	Report on data analysis
5.8	Interface with other processes
6	Review of the post-market surveillance plan
6.1	Purpose of the review
6.2	Criteria
6.3	Review
Annex A	(informative) Examples of data sources
Annex B	(informative) Examples of data analysis methods
B.1	General
B.2	Overview table: data analysis methods
B.3	Descriptive methods for trend analysis
B.4	Descriptive method: Bar charts
B.5	Descriptive method, Pareto analysis
B.6	Qualitative techniques
Annex C	(informative) Examples of post-market surveillance plans
C.1	Example of a post-market surveillance plan for a surgical scalpel
C.1.1	General
C.1.2	Scope of the post-market surveillance plan
C.1.3	Objective of the post-market surveillance plan
C.1.4	Responsibilities and authorities
C.1.5	Data collection
C.1.6	Data analysis
C.1.7	Report on data analysis
C.1.8	Review of the post-market surveillance plan
C.2	Example of a post-market surveillance plan for a radiation therapy system

C.2.1	General
C.2.2	Scope of the post-market surveillance plan
C.2.3	Objective of the post-market surveillance plan
C.2.4	Responsibilities and authorities
C.2.5	Data collection
C.2.6	Data analysis
C.2.7	Report on data analysis
C.2.8	Review of the post-market surveillance plan
C.3	Example of a post-market surveillance plan for a drug eluting stent
C.3.1	General
C.3.2	Scope of the post-market surveillance plan
C.3.3	Objective of the post-market surveillance plan
C.3.4	Responsibilities and authorities
C.3.5	Data collection
C.3.5.1	Passive/reactive feedback
C.3.5.2	Proactive feedback
C.3.6	Data analysis
C.3.6.1	General
C.3.6.2	Post-market clinical follow-up studies
C.3.7	Report on data analysis
C.3.8	Review of the post-market surveillance plan
C.4	Example of a post-market surveillance plan for a blood glucose monitoring system
C.4.1	General
C.4.2	Scope of the post-market surveillance plan
C.4.3	Objective of the post-market surveillance plan
C.4.4	Responsibilities and authorities
C.4.5	Data collection
C.4.6	Data analysis
C.4.7	Report on data analysis
C.4.8	Review of the post-market surveillance plan
C.5	Example for large IVD analyser
C.5.1	General
C.5.2	Scope of the post-market surveillance plan
C.5.3	Objective of the post-market surveillance plan
C.5.4	Responsibilities and authorities
C.5.5	Data collection
C.5.6	Data analysis
C.5.7	Report on data analysis
C.5.8	Review of the post-market surveillance plan