WHITEPAPER

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PMS Proactive & Reactive Data Sources for Devices

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PMS processes are generating data, either continually or intermittently. Staff members from processes and subsystems within the organization that interface with PMS (CAPA improvements, clinical evaluations, design & development, vigilance, risk management) are expecting a level of analysis on PMS data for their own decision-making purposes. PMS knowledge management is a proactive, cross-functional process that includes holistic planning, checking, action, and standardization of creation, usage, sharing, and maintenance of organizational PMS data. Data sources are key to this. They can be classified as active or passive sources, and a good PMS data collection system should use a combination of the two.

Examples of data sources which can be considered by the organization for the purpose of post-market surveillance include:

Data Source	Details	Information useful for
Complaints, including adverse events reported to the organization	According to the definition, a complaint communicates a deficiency related to the medical device's identity, quality, durability, reliability, usability, safety or performance. Complaints are often individual cases, which should be processed one by one. Complaints are potentially the source for regulatory reportable events. It is best practice, that any adverse event be initially treated as a complaint. Applicable regulatory requirements for the further processing of adverse events should be followed. Reports on events should include details on type of event, medical de-vice, (or of the component involved), quantity of devices or components, severity/patient condition, user de- tails (physician, healthcare facility, healthcare professional, patient, time period of events etc.). Over a period of time, a trend analysis of complaints can be performed. Complaints should be considered in every post-market surveillance plan. Satisfying applicable regulatory requirements on the reporting of adverse events. Detecting early any unexpected problems experienced by users and patients.	Satisfying applicable regulatory requirements on the reporting of adverse events. Detecting early any unexpected problems experienced by users and patients. Analysing the occurrence of problems. Deciding whether an advisory notice and its associated field action (also known as recall) are appropriate. Initiating corrective or preventive actions. Reviewing the medical device risk management file. Determining the need for improvement of the medical device (i.e. medical device and related services). Reviewing the controls in place throughout the quality management system.

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	Analysing the occurrence of problems. Deciding whether an advisory notice and its associated field action (also known as recall) are appropriate. Initiating corrective or preventive actions. Reviewing the medical device risk management file. Determining the need for improvement of the medical device (i.e. medical device and related services). Reviewing the controls in place throughout the quality management system.	
Maintenance (including preventive maintenance / corrective maintenance and repair / refurbishing)	Records should include details on medical device type, medical device identifier (e.g. lot, batch, serial number), medical device configuration, user location, infrastructure (fluids, electric current), failure mode, acceptance activities, updates implemented, parts replaced (identity, number), usage of the medical device, servicing personnel, date of servicing.	The analysis of maintenance service reports can generate useful information to determine the reliability of the medical device. Some reliability indicators such as “mean time between failure” can highlight changes in the reliability of the medical device. The generated information can also be useful to re-evaluate the preventive maintenance schedule. It can also enable detecting unanticipated failure modes. Service reports can highlight malfunctions potentially or actually leading to adverse events, in which case they are also to be handled as complaints.
Installation	Installation records should contain details on the medical device, including its configuration, acceptance activities completed and their status, the identity of the installation personnel, and the installation date, as well as the user location and infrastructure (fluids, electric current). Installation can also include the training to the users and the effectiveness of such training, for instance through direct witnessing of the use of the medical device by their intended users, and the first use failure to appreciate the learning curve.	The primary purpose of installation records is to ensure that the released medical devices meet their intended quality criteria for safety and performance, regardless whether the installation was performed by internal resources or outsourced. The analysis of installation records can highlight unforeseen situations where the medical device cannot be installed or does not operate as expected, or other hazardous conditions, due to the infrastructure, environment and interactions with other medical devices or user profiles.

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Returned medical devices	The information to record about returned medical devices includes details on the medical device identity, the returned quantity, the reasons for returning the medical device, the customer, any defects claimed by the customer or observed by the organization, the disposition. Reasons for returning a medical device are varied and not all tied to concerns related to the safety or performance of the medical device. An organization should consider whether the returned medical device was used or damaged, whether the claimed concern could impact the safety or performance of the medical device if occurring while being used on or by a patient, whether the returned medical device may be distributed again (after reprocessing or reinspection, if appropriate). It is common for implant sets and the associated surgical instruments to be shipped to a healthcare facility to perform a procedure and returned to the organization. When returned, the organization examines the used medical devices to replenish the set and verify the quality and functionality of the various components of the set. This can enable the organization to determine the impact of repeated reprocessing on the medical devices.	A medical device can be returned to the organization for various reasons. Some of these reasons for the return can qualify as a complaint (see above). The analysis of a medical device quality and performance after repeated reprocessing can provide predictive information on the longevity of the medical device, and their need for maintenance or periodical reinspection. Returned medical device can provide insight into possible causes for product issues.
Explants	An organization manufacturing implantable medical devices should encourage healthcare facilities to retrieve, preserve and return explanted medical devices in a way that is appropriate for their analysis. The organization should therefore also be prepared to receive, handle and analyse such retrieved explanted medical devices. See ISO 12891 for additional details on retrieval and analysis of surgical implants.	An organization manufacturing implantable medical devices should encourage healthcare facilities to retrieve, preserve and return explanted medical devices in a way that is appropriate for their analysis. The organization should therefore also be prepared to receive, handle and analyse such retrieved explanted medical devices. See ISO 12891 for additional details on retrieval and analysis of surgical implants. The investigation of retrieved surgical implants, adjacent tissues, and associated fluids can be undertaken to: ~ determine the cause of a clinical complication or surgical implant failure;

Data Source	Details	Information useful for
		~ improve knowledge of surgical implant performance and safety; ~ improve knowledge of the interactions of surgical implants and human tissues; ~ develop materials with improved biocompatibility and implants with improved functional longevity.
Medical device registries	Medical device registries are tools for the identification and study of medical devices outcomes. Medical device registries are used for many purposes, including short and long term surveillance, fulfilment of post-market observational study commitments for regulatory bodies, and comparative safety and effectiveness assessments, including those in under studied subpopulations. Unlike clinical trials, medical device registries allow assessment of medical device performance in a real world setting. Registries contain data on large numbers of patients receiving care in diverse clinical settings and include clinical outcomes over time, thus providing a critical platform for capturing the experience with a medical device throughout the medical device life cycle. Moreover, by linking medical device exposures and long term outcomes, registries permit follow up that can span decades. See Registries for Evaluating Patient Outcomes: A User's Guide from the Agency for Healthcare Research and Quality for detailed information. NOTE: The term "medical device registry" as used here is not to be confused with the concept of medical device registration by regulatory authorities.	Because registries systematically collect the information from the use of all medical devices for a defined medical procedure, they generate information of high scientific value to establish the actual safety and performance of the medical device. If the protocol provides for it, it can include information on the long term behaviour of medical devices, which is especially relevant for implantable medical devices, and enables establishing their long term survival curve. The analysis of the collected information enables to reliably verify the risk estimation relative to complications and undesirable effects, including reportable adverse events. Registries focusing on the medical procedure collect information relative to all medical devices used for that procedure and enables the comparison of performances and safety profile between the various medical devices. Registry information can also be leveraged to support application for marketing authorizations of a medical device to new markets, or for the extension of their intended use according to the medical practice, or of the next generation of medical devices. Registries generate high quality data that can be used to draw scientifically valid conclusions. They should be used when relevant as real world evidence.
Post-market clinical follow-up (PMCF) studies	A PMCF study is carried out following marketing approval intended to answer specific questions relating to clinical safety or performance (i.e. residual risks) of a medical device when used in accordance with its approved labelling. It can examine issues such	Clinical data related to residual risks, review of long term safety or performance, occurrence of clinical events and those events specific to defined patient population, safety or performance of the medical device in representative population of users and patients

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	as long term performance and survival, the occurrence of clinical events (such as delayed hypersensitivity reactions or thrombosis), events specific to defined patient populations, or the performance of the medical device in a more representative population of providers and patients, see also GHTF/SG5/N1, ISO 14155:2019, and ISO 20916 (for in-vitro diagnostic medical devices). PMCF studies might be the continuation or extension of a pre-market clinical investigation. See GHTF/SG5/N4 for more detailed information. The protocol of PMCF studies should ensure the high quality of the clinical data collected. NOTE [1]: because regulatory requirements for marketing authorization vary between jurisdictions, a pre-market clinical investigation in one jurisdiction can be seen as a post-market clinical follow-up study in another, and vice versa. NOTE [2]: Additional information related to circumstances that can result in the need for post-market clinical follow-up studies can be found in GHTF/SG5/N4:2010.	Outcomes of the adequacy of clinical data to address the safety, performance, benefit/risk profile, claims and side effects. Because PMCF studies generate high quality data, they can be used to draw scientifically valid conclusions that can be considered as real world evidence.
User training	An organization can decide to train users to prevent the misuse of the medical device and shorten the learning curve on how to use it. This could be necessary to mitigate identified risks and is particularly relevant in case of innovative medical devices, necessitating the users to adapt their medical practices.	User training is an opportunity to observe the users, understand their thought process and challenges, and estimate the distribution of user skills. Medical device organizations tend to engage during the design and development of a medical device with highly experienced health practitioners, whose skills are above average. User training is an opportunity to confirm the usability of the medical device to the general population of users. Feedback from user training can provide insight into new risks due to unforeseen user interaction with the medical device and possibilities for improvement.

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Scientific literature	Published scientific literature can include various types of information, for example: ~ analysis of registries; ~ results of prospective clinical trials, randomized or not; ~ results of cohort follow-up studies; ~ report on individual cases; ~ new techniques, technology, therapies and other innovations. Scientific literature on a medical device can describe cases that could be seen as complaints (see above).	Outcomes of the adequacy of clinical data to address the safety, performance, benefit/risk profile, claims and side effects. Because PMCF studies generate high quality data, they can be used to draw scientifically valid conclusions that can be considered as real world evidence.
	Scientific literature related to a medical device can offer clinical evidence to its manufacturer or manufacturers of similar medical devices that identify additional risk or support clinical data/ performance evaluation results, which cannot be identified in existing documentation. The value and scientific validity of the published information can vary and should be determined considering factors such as: ~ whether the object of the published information is the organization's medical device, a similar medical device or a medical device presenting some similarities with the organization's medical device; ~ the methodology of the study; ~ whether the publication is peer reviewed.	The extent to which valid conclusions on a medical device's continued safety and performance can be drawn from published literature depends on the scientific validity of their conclusion and the degree to which they apply to that medical device.
Market surveillance activities by regulatory authorities and their related publications and recommendations	Regulatory authorities publish warnings and safety alerts, that can cover a single medical device or a broad category of medical devices. Such information generally requires immediate attention or action to en- sure public health, by manufactur- ers, healthcare professional, users or patients. Regulatory authorities also publish the result of their evaluation of medical technologies, as well as guidance on the use of these technologies.	Warnings and safety alerts issued by the regulatory authorities is part of the critical sources for early identification of major public health issues and can trigger immediate actions by an organization, such as the clarification of instructions for use, or some containment actions, including advisory notices. The evaluation of medical technol- ogies by regulatory authorities describe the state of the art to which an organization can compare their medical devices.

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	An organization should include this source of information in their post-market surveillance plan and determine whether the published information is relevant to their medical device, and its significance.	The extent to which valid conclusions on a medical device's continued safety and performance can be drawn from evaluation of medical technologies by regulatory authorities, as a result of their market surveillance activities, depends on the scientific validity of their conclusion and the degree to which they apply to that medical device.
Publicly accessible databases from regulatory authorities on adverse events and advisory notices.	Adverse events databases can contain information about events with similar medical devices. Collecting such information can allow insight into events that could also occur with the medical device for which the post-market surveillance plan is applicable. To be able to judge the applicability of events occurring with other medical devices, the similarities and differences between the original and the similar medical device should be available. Some regulatory authorities' databases on adverse events are publicly accessible (e.g. DAEN in Australia, MedSun or MAUDE in the USA). However, the ability to extrapolate information from regulatory authorities' databases to a particular medical device is often limited, considering the many biases associated with the submitted data.	Information on adverse events related to similar medical devices can enable identifying potential hazards applicable to a medical device, or prioritize identified risks considering their apparent prevalence. NOTE: The ability to rely on such information as evidence of safety or performance is limited.
Regulatory requirements, standards, guidances and best practices	Medical device organizations should monitor applicable regulatory requirements for any change to evaluate upcoming gaps, and plan for continued compliance. Standards, guidance documents and best practices are not mandatory requirements (see regulatory requirements), but describe the state of the art.	Changes in regulatory requirements, standards, guidance documents and best practices can suggest a change in the state of the art, impacting design and development inputs and potentially requiring design and development changes (e.g. restricted use of a chemical). They can also offer opportunities for organizations to consider (e.g. use of real world evidence as an alternative to premarket clinical investigation).
Social media	Social media are platforms to exchange thoughts and ideas. Most of them are not moderated and even when they are, it does not guaranty the truthfulness of the published information.	The reliability of the information on social media can be difficult to confirm. Information on social media should therefore be used with caution.

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	Monitoring social media at large is unrealistic and most probably unreliable. However, organizations that set their own space as a two way communication channel on social media platforms should monitor the information posted by external individuals on their space as feedback.	Feedback posted on an organization social media space can concern any aspect of the organization and their medical devices and can be positive or negative. Negative feedback related to the organization's medical devices can include complaints (see above).
Medical device distribution and medical device tracking	This relates to any traceability or distribution issues that can impact medical device quality. Testing of distribution systems can be useful to identify risks to traceability, storage and other issues that can impact on quality and delivery. Distribution records and sales analysis can be used to identify variations in the use of the medical device depending on the region, the practitioner, or other factors. The analysis can reveal trends that are patient related (for example, a population of short people can use smaller medical device sizes than a population of taller or heavier people) or for non patient related reasons, like a physician's preference for undersized medical devices, which could suggest a different risk profile and patient prognosis.	Confirming the robustness of traceability / tracking system Identifying patterns suggestive of difference in usage of the medical device.
Finished products, product quality information	This includes inspection and test records, summary of scrap, first pass acceptance rate. This also includes non conformance reports, process performance measures, e.g. statistical process control data.	Establishes manufacturing efficiencies and provides quality data for traceability in the event of complaints and events that can occur post market.
Internal audits and external inspections	This includes results of a regulatory audit, clinical audit or an inspection based on the following factors: ~ risk of the medical device; ~ the medical device's frequency of non-compliance; ~ specific information to suspect non-conformities of the medical devices or the quality management system.	Data derived through such activities is important to include within an organization's design and development and risk process and drives the quality requirement for continual development.

Data Source	Details	Information useful for
Market/customer inputs: *competitor's research*	Information on experience and research with similar medical devices	Provides input for the state of the art and can be used as part of an organization's design and development and risk management process.
Market/customer inputs: *customer preference surveys*	This includes detail on the customer segment queried versus the entire population of users, summary of results, and data obtained from similar medical devices or therapies made by the same or different manufacturer, manufacturer experience and history.	Data derived through such surveys is important to include within an organization's design and development and risk management process and drives the quality requirement for continual development.
Market/customer inputs: *solicited data on new or modified medical devices*	This includes data on customer population queried versus entire population of users.	These data are important to include within an organization's design and development and risk process, and drives the quality requirement for continual development.
Market/customer inputs: *meetings with medical experts, key opinion leader meetings or panels*	This includes summary of discussions and outcomes.	These data are important to include within an organization's design and development and risk process, and drives the quality requirement for continual development.
Market/customer inputs: *patient group experience of using medical devices, or encounters with them during episodes of treatment*	This includes summary of discussions and outcomes.	These data are important to include within an organization's design and development and risk process, and drives the quality requirement for continual development.
Market/customer inputs: *user interaction with the organization (sales workforce and customer service)*	This should be documented, preferably using a standard format.	These data are important to include within an organization's design and development and risk process, and drives the quality requirement for continual development.
Market/customer inputs: *user reactions during training programmes*	This includes surveys immediately following training.	Data derived through such training is important to include within an organization's design and development and risk process and drives the quality requirement for continual development. This can also provide feedback on use and misuse.

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