



Effective post-market surveillance

Understanding and conducting vigilance
and post-market clinical follow-up

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Introduction

In order to comply with the European Union (EU) Medical Device Directives – 90/385/EEC Active Implantable Medical Devices (AIMD), 93/42/EEC Medical Device Directive (MDD) and 98/79/EC In Vitro Diagnostics Device Directive (IVDD) (referred to as 'The directives' hereafter), manufacturers must conduct post-market surveillance (PMS). As outlined in the quality assurance area of the annexes of these directives, PMS requires:

1. that the manufacturer institute and maintain an up-to-date systematic procedure to review experience gained from devices in the post-production phase, which include provisions referred to in Annex X (93/42/EEC), or Annex VII (90/385/EEC) and;
2. the implementation of appropriate means to apply any necessary corrective action.^{1,2,3}

The directives' requirements are complemented by harmonized standards EN ISO 13485, *Medical Devices*⁴ and EN ISO 14971:2012, *Medical devices: Application of risk management to medical devices*.⁵ EN ISO 13485 gives an outline of a quality management system (QMS) structure which compels the need for a feedback system specifically to provide early warning of quality problems and for input into corrective and preventive action processes. In addition to the pre-market assessment of risks associated with a new device, EN ISO 14971:2012 specifies requirements for production and post-production information to be considered as part of the overall risk assessment process throughout the life of the device.

The directives, in conjunction with the harmonized standards, form a framework for manufacturers to develop a comprehensive feedback system intended to ensure the continued safe-use of a device for the manufacturer's intended purpose.

What are the requirements of post-market surveillance?

PMS is a collection of processes and activities used to monitor the performance of a medical device. These activities are designed to generate information regarding use of the device to expediently identify device design and/or usage problems and accurately characterize the real-world device behaviour and clinical outcomes. The need for PMS arises immediately upon commercialization of the device.

Ensuring adequate medical input into the risk management process during product development will help manufacturers characterize possible product safety issues. The risk profile of the device evolves from these efforts and can be used to effectively develop the PMS strategy for the device. It is important to note that the requirements for PMS should be directly proportional to the risk associated with the device based on its intended use.

In developing a robust PMS process, manufacturers should consider whether or not the product or technology is new to the manufacturer and/or the marketplace. Where a manufacturer has a long history of development and marketing of similar device types, they are likely to have a clear understanding of the patient population and the reasonably foreseeable risk associated with the device. Available data regarding state-of-the-art market experience for similar products and technology may be adequate for low-risk devices with a long history of clinical use. For those manufacturers pursuing the literature route to support clinical evaluation requirements,^{2,6} these data types often give the manufacturer knowledge of the patient population, co-morbidities and the effect of different patient demographics for the use of the device. Literature of high quality (e.g. randomized control trials, meta-analysis) will give manufacturers quantified clinical data regarding the safety profile of these device types.

In the case of new technology, manufacturers often have a limited understanding of the patient population and the complexities of the disease state, which may affect the performance of the device. This limited knowledge may result in under or over representation of risks in the pre-market assessment of the device design and its interaction with the patient/user. Manufacturers introducing technology new to the organization should respond accordingly with an increased monitoring program to ensure early detection of problems not foreseen in development. Also of concern is the extent of available scientific knowledge for new devices. In the case of novel or new treatments, knowledge of long-term effects may be limited. Post-market clinical follow-up (PMCF) may be warranted to ensure adequate characterization of the real-world clinical use of the device.

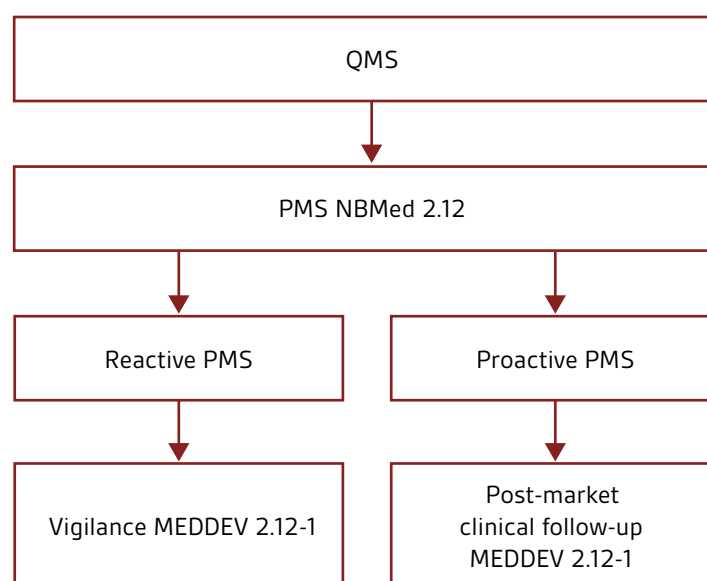
PMS could be 'reactive' – responding after an event; of which there are many types ranging from complaints to those involving serious injury or in an extreme case where a serious injury or death has occurred known as 'Vigilance'. These activities can be considered 'passive' as they are largely data collection activities. On the other hand, PMS could be 'proactive' – endeavours meant to anticipate and curtail events before they occur; there are many types such as user surveys, manufacturer-sponsored clinical registry studies, PMCF studies. In 'proactive' PMS activities, information is actively sought to gain insight and data into the real-world performance of the device.

As shown in Table 1, the flow of information into risk management comes from a wide variety of activities and individuals including patients, physicians, healthcare facilities, regulatory authorities, professional societies, researchers and internal personnel. Analysis and review of PMS data is part of the risk management process and should be performed by manufacturers on a routine basis. Ideally, these reviews are performed during formal management reviews.

Table 1 – Examples of PMS data and their respective action types

Proactive	Reactive
<ul style="list-style-type: none"> • Customer surveys • Post CE mark clinical trials, including PMCF • Manufacturer sponsored device tracking/implant registries • Expert user groups (focus groups) 	<ul style="list-style-type: none"> • Customer complaints • Unsolicited user feedback (other than complaints) • Maintenance/service reports • In-house testing (routine) • Failure analysis • Social media • Literature reviews • Regional or national device registries (non-manufacturer sponsored trials)

Figure 1 – Relationship between QMS, reactive PMS and proactive PMS





To comply with the MDD, manufacturers should conduct PMS

PMS requires that manufacturers detail how often key documentation, that is used to demonstrate conformity to the essential requirements (ERs) will be updated in response to information gained during the PMS.^{1,2,3} It is important to note that a combination of 'proactive' and 'reactive' PMS activities form the basis of the device's PMS plan. A PMS plan must be provided as part of the assessment for CE mark certification and should be based on available clinical data and an assessment of residual risks.

Regardless of the particular device or implementation of a PMCF trial, manufacturers still need to perform the 'reactive' post-marketing activities that include vigilance, complaint handling, and reviews of clinical literature and databases. PMS requirements outlined in the directives require a manufacturer to notify the competent authorities of serious device-related events, known as 'incidents' immediately upon learning of them.^{1,2,3} This implies that during the post-production phase, manufacturers must have an established system for vigilance that is appropriate for gaining and reviewing experience in the post-production phase from the range of devices manufactured.

When formulating the device PMS plan, it is pertinent to remember that ISO 13485 applies to all medical devices on the market and in the context of this standard, 'early warning' means proactive PMS. A PMCF study is expected as part of a post-market surveillance plan. There should be an adequate rationale if a PMCF study is deemed unnecessary.

As products are the output of various processes within a quality management system, it is beneficial to discuss vigilance, post-market clinical planning and data as a critical part of the design dossier and/or technical documentation of a device. Two processes which warrant specific focus are the 'reactive' vigilance process and 'proactive' PMCF activities.

What is the value of a vigilance system?

Pre-market data is often a major determinant for the development and placement of medical devices. Unfortunately, pre-market data is based on design, and test-model assumptions that may not accurately represent real-life situations. In addition, pre-market data typically reflect 'short term' periods of observation or use, and may not reflect potential incidents or adverse information that would arise over longer periods of time i.e. during the post-market phase. Given these considerations, a properly implemented vigilance system, which involves the cooperation of users, manufacturers, competent authorities, and others could effectively facilitate the detection of previously unknown adverse product information and prevent future recurrence of incidents that might have otherwise led to death or serious deterioration in health.

What is the vigilance guidance document?

These guidelines describe the European system for notification and evaluation of Incidents and Field Safety Corrective Actions (FSCA) regarding medical devices; this is known as the Medical Device Vigilance System (MDVS). The MDVS is intended to facilitate a direct, timely, and harmonized implementation of FSCA across the Member States where the device is in use by manufacturers that are working closely with their notified bodies (NBs). The latest revision of the vigilance guidance document is MEDDEV 2.12-1 Rev. 8, which became applicable as of July 2013. This version explicitly includes in vitro fertilization/artificial reproduction technologies (IVF/ART) devices within the scope of the vigilance system and provides clarity in relation to devices that are not intended to act directly on the individual.⁷

The scope of these guidelines is relevant to 'incidents' occurring within the member states of the EEA, Switzerland and Turkey with regard to the following:

- a) Devices which carry the CE mark.
- b) Devices that do not carry the CE mark but fall under the scope of the directives (e.g. custom-made devices).
- c) Devices that do not carry the CE mark because they were placed on the market prior to the implementation of the directives.
- d) Devices that do not carry the CE mark but where such 'incidents' lead to (a) *corrective action(s)* relevant to the devices mentioned in a), b) and c).

In order to promote a common approach by manufacturers (and authorized representatives), NBs, national competent authorities, and users, the guidance document sets forth general principles that should be followed, including uniform reporting requirements and detailed definitions to assist manufacturers in discerning whether an event rises to the level of a reportable 'incident'.

An 'incident' is defined as any malfunction or deterioration in the characteristics and/or performance of a device as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient or user or other persons or to a serious deterioration in their state of health.

A serious deterioration of health is defined as a:

- life-threatening illness;
- permanent impairment of a body function or permanent damage to a body structure;
- a condition necessitating medical or surgical intervention to prevent the above;
- fetal distress, fetal death or any congenital abnormality or birth defect.

Manufacturers should not be quick to dismiss events in which actual harm was not caused. Device malfunctions which could cause or contribute to a death or serious deterioration in health must be reported. A thorough investigation to determine the cause of such events should be performed, as these events are opportunities to correct an unintended fault mode in advance of harm being done.

Requirements for periodic summary reporting, trend reports and handling of unusual event conditions such as error/abnormal use events are thoroughly defined and described in this comprehensive guidance. Of particular note, are the defined event conditions which do not require reporting under MDVS such as events caused by patient conditions, device deficiencies found prior to its use, properly functioning fault-protections and expected and foreseeable side effects.

As common among regulatory authorities, required timelines for reporting correspond to the risks associated with public health. Timelines for the initial reporting of an incident is interpreted as 'immediately, without any unjustified delay'. Timelines for the three main incident categories are:

- serious public health threat – two calendar days after event discovery by the manufacturer;
- death or unanticipated serious deterioration in health – 10 elapsed calendar days following the date of event discovery;
- others – not later than 30 days elapsed calendar days following the date of event discovery.

Information to include in the report as well as details regarding to whom the reports should be made are clearly outlined in the guidance document, as are the roles and responsibilities of all parties, including the competent authorities as well as the role of the EU Commission in facilitating an effective MDVS.

NBs do not play an operational role in the MDVS but do provide support by: (1) assessment of vigilance procedures, audit of procedure implementation and its integration with other systems, (2) assessment of the impact of vigilance issues on certification, and (3) acting as a liaison between the manufacturer and the national competent authority (if required).

While not explicitly identified as a component of the MDVS in the guidelines, user input and feedback is vital for vigilance. Users report suspected incidents to manufacturers and user interaction and cooperation with the manufacturer is necessary for the implementation of FSCA.

The final section of the guidance document provides a list of annexes and forms which are useful in the successful implementation of a MDVS.⁷

An overview of the PMCF guidance document, scope and revisions

The revisions to the PMCF guidance document, MEDDEV 2.12-2 Rev. 2, reflect an emphasis on long-term clinical data, and underscore the importance of detailed documentation that is required for post-market clinical studies as a part of an appropriate PMCF plan. The document provides guidelines and support for the creation of risk-based PMS plans in accordance with existing guidance documents and International Organization for Standards (ISO) relevant to clinical data plans, analysis, and final reporting. It also provides details on the role of NBs in PMCF.⁸ NB review and approval of PMCF is mandatory.

It is important to note that PMCF plans are not only relevant for high-risk devices. For example, residual risk (risk that remains after control measures have been taken during the pre-market phase or at other steps) is the primary type of risk that is addressed in the post-marketing phase. Residual risk includes known or emerging risks and potential risks due to statistical limitations.⁸ PMCF plans are beneficial for any class of device that is affected by defined parameters known to contribute to residual risk. MEDDEV 2.12-2 Rev. 2 outlines specific circumstances that contribute to residual risk.

As provided by the MEDDEV 2.12-2 Rev. 2, the circumstances under which PMCF may be necessary, include but are not limited to:

- novel medical technology;
- high product-related risk;
- high-risk anatomical locations;
- high-risk target populations (e.g. children, elderly);
- severity of disease/treatment challenges;
- unanswered questions of long-term safety and performance;
- identification of previously unstudied subpopulations which may exhibit different benefit/risk-ratio (i.e. hip implants in different ethnic populations);
- verification of safety and performance of device when exposed to a larger or a more varied population of clinical users.

As emphasized in the guidance document, manufacturers who used literature concerning similar devices to demonstrate ERs, and CE-mark the device, may need to collect data on their own devices in the PMCF. It is noteworthy that a justification for no pre-market clinical investigation is not the same as the justification for no PMCF.

PMCF studies may include extended patient follow-up times for pre-market studies, new clinical investigations, or a review of relevant retrospective data from patients previously exposed to the device.

Elements of PMCF studies include:

- clearly stated objective(s);
- scientifically sound design with an appropriate rationale;
- logical study plan and implementation;
- appropriate statistical analysis of data, interpretation, and conclusion.⁸

Arguably, the requirements for PMCF studies do not differ greatly from those of other pre-market clinical study plans. A PMCF study must: (1) demonstrate, for its intended use, clinical safety and performance of a device through its lifetime and (2) exhibit the device's performance to a broad spectrum of physicians and patients. However, the PMCF does not have to include randomization, excessive patient selection criteria, or control groups in order to demonstrate device performance and safety.

PMCFs should have adequate interim follow-up periods for early detection of problems as well as long term follow-up. Manufacturers should plan accordingly for anticipated loss to follow-up, as some patient groups are prone to significant drop out rates due to their disease condition, age or related co-morbidities.

PMCF plans should be formal. Manufacturers should take care to ensure documentation prepared for PMCF is as logically organized and controlled as the documentation prepared and used in a pre-market clinical trial.

EU NBs are equipped to assess a manufacturer's PMCF plans, their proposed execution, and any proposed justification that a PMCF is not necessary. A thorough understanding and implementation of the guidance document will facilitate interactions between manufacturers and NBs during the review/audit process and will provide a seamless execution of the PMCF plan as part of the overall PMS process.

Balancing pre-market and post-market clinical data guidelines

MEDDEV 2.12-2 Rev. 2 aims to create a manufacturing and clinical environment that better supports long-term safety and performance of medical devices through PMCF. Is a PMCF still required if a manufacturer has existing long-term clinical data from the pre-market phase (whether through clinical investigation, literature search, market equivalence or another method)?

In the European system, even if a device has gained CE marking based on clinical evidence from substantially equivalent similar device(s), it is likely a PMCF will be required. If the manufacturer has provided long-term clinical data on the device itself, that demonstrates state-of-the-art safety and performance for the device's intended use(s), a PMCF may not be necessary. In these cases, the purpose of the PMCF has already been met.

To help manufacturers determine when pre-market data is not sufficient to fulfil the need for a PMCF, MEDDEV 2.12 Rev. 2 outlines the 'limitations in the clinical data available in the pre-market phase,' including:

- a limited number of subjects;
- a narrow diversity in study population;
- relative homogeneity of subjects and investigators (users);
- an imbalance between use under controlled variables versus use under a full range of conditions encountered in general medical practice.

The guidelines further suggest 'complete characterization of all risks may not always be possible or practical in the pre-market phase.' It may also be prudent for manufacturers to ask themselves the following questions to help guide the justification for either conducting or foregoing a PMCF:

- Does pre-market clinical data reveal any unanswered questions about safety or effectiveness?
- Did any adverse events occur that warrant further investigation?
- Was pre-market clinical data improperly generalized?
- Does the lifespan of the device extend beyond the time frame that pre-market clinical data was collected?
- Has new information emerged that affects pre-market data?
- Has the use of the device been extended to populations that were not included in clinical trials?
- Has the product been altered in any way from the product that was used to gather pre-market clinical data?

What are the additional guidance documents informing post-market clinical follow-up?

The MEDDEV 2.12-2 Rev. 2 is supported and supplemented by additional guidance documents and ISO standards that provide direction for obtaining relevant, long-term data from any clinical investigation (whether a part of pre- or post-market plans). Among these guidelines are common factors and priorities that guide the competency of clinical studies and help determine if clinical data is substantive and robust.

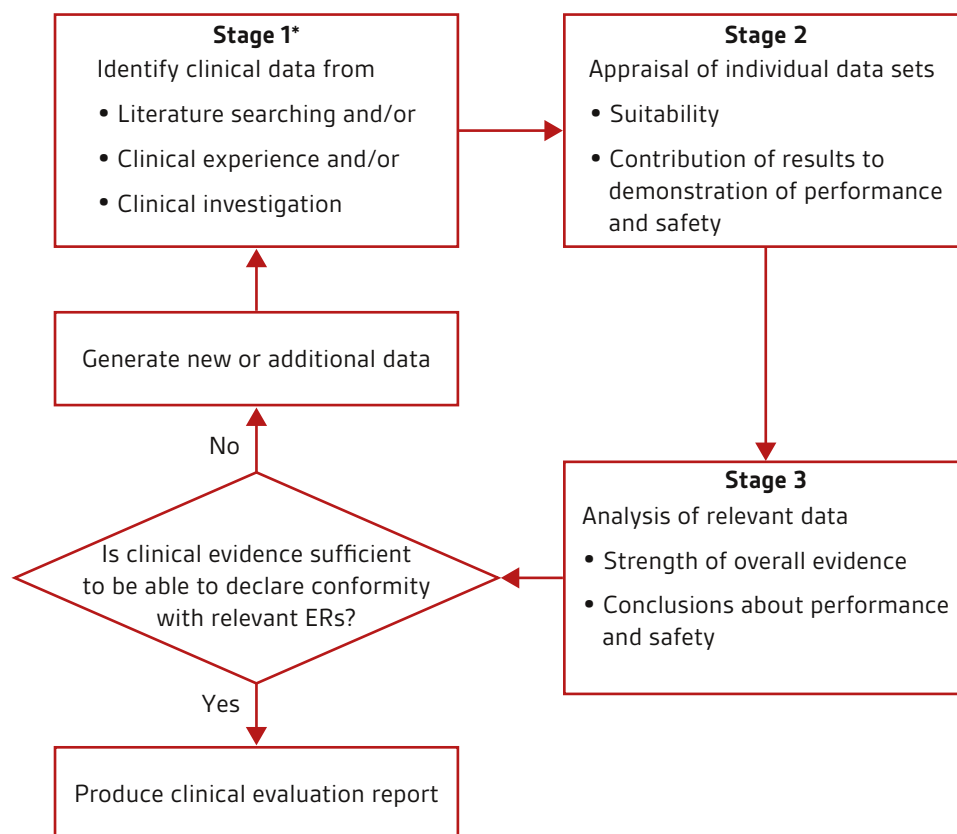
- EN ISO 14155:2011 defines good clinical practice for the design, conduct, recording, and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes. This standard specifies general requirements intended to protect the rights, safety, and well-being of human subjects; ensures the scientific conduct of the clinical investigation and credibility of the results; define the responsibilities of the sponsor and principal investigator; and assist sponsors, investigators, ethics committees, regulatory authorities, and other bodies involved in the conformity assessment of medical devices.⁹
- MEDDEV 2.7.1 Rev. 3 outlines the stages of clinical evaluations; the general principles of a thorough, objective, and ethical clinical evaluation; the sources of data, appraisal, and analysis of clinical data; and the necessary reporting.⁶
- MEDDEV 2.7.3 gives guidance on what is reportable in a clinical investigation as 'incidents' are not 'adverse events'.¹⁰
- MEDDEV 2.7.4 focuses mainly on pre-market clinical investigations, but provides relevant best practices for any clinical investigation.¹¹

Communication with notified bodies

Given the presence of several interacting and authoritative guidance documents and standards, all of which create a set of larger, more comprehensive guiding principles for PMCF, good communication between the manufacturer and the NB is essential. Manufacturers should confer with their NB on the adequacy of the PMCF design to ensure compliance with all ERs.

When working with NBs to review a PMCF plan, the process is most efficient and beneficial to manufacturers when it is initiated during the early stages of development. Early feedback on proposed plans allows NBs to challenge any elements that will not stand up to scrutiny, thereby eliminating delays during the final review process. An experienced and knowledgeable NB will clearly communicate with manufacturers and provide reasons why a plan fails to meet requirements. Common examples of problem areas include:

- insufficient clinical measures (e.g. assessment time intervals and overall duration; assessed outcome measures);
- insufficient patient enrolment numbers, which would not account for potential loss to follow-up over the study duration;
- covering all indications;
- covering all devices related to the design dossier or technical documentation.

Figure 2 – Stages of clinical evaluation

*Conformity to harmonized performance standards may be sufficient to demonstrate compliance to relevant essential requirements (ERs)

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Working early and maintaining consistent communication with an NB will help ensure that any necessary changes can be made in a timely manner.

A global shift: The need for PMCF data

The purpose of any medical device is to make significant improvements to a patient's quality of life, and manufacturers are facing increasing pressures to provide detailed technical documentation of clinical data, beyond pre-market findings, that demonstrate continued safe, effective use. This evidence should support any and all claims and indications regarding the device.

The emphasis in legislation on post-market clinical data is becoming increasingly more prevalent. The revisions to MEDDEV 2.12-2, in support of the MDD 93/42/EEC, and considering the amendments made by Directive 2007/47/EC, are indicative of the laws that currently govern EU requirements, and there are continued legislative efforts to make PMCF and PMS an even more authoritative presence within the law.

For example, the draft EU Medical Devices Regulations published in September 2012 incorporates verbatim the MEDDEV guidance on both vigilance and PMCF.

Real-market situations provide a good illustration of the need for this focus. For example, after recent complications with PIP breast implants and metal-on-metal hip implant devices, the EU Commission urged member states to tighten controls, increase surveillance, and restore full confidence in the EU CE marking regulatory system. The commission proposed the following:

- Verify that NBs are designated only for the assessment of medical devices and technologies that correspond to their proven expertise and competence.
- Ensure that all NBs exercise the authority given to them by law to ensure that manufacturers conform to regulations through assessment (e.g. power to conduct unannounced inspections).
- Reinforce market surveillance by national authorities (e.g. spot checks for certain types of devices).
- Improve the impact of the vigilance system for medical devices:
 - Provide systematic access for NBs to reports of adverse events.
 - Encourage healthcare professionals and patients to report adverse events.
 - Enhance coordination in analysing reported incidents in order to pool expertise and speed up necessary corrective actions.
- Support the development of tools to ensure the traceability of medical devices and their long-term safety and performance monitoring (e.g. Unique device identification systems and implant registries).¹²



User input and feedback is vital for vigilance

These objectives, however, are not isolated to the EU. In 2012, the Center for Devices and Radiological Health (under USFDA¹³ jurisdiction) released its strategic priorities, the first of which emphasizes the complete implementation of a 'total product lifecycle approach' and includes the following post-market goals:

- Develop a comprehensive strategy to assess real-world device performance.
- Post a proposed strategy (accessible online) to assess real world device performance and seek public input.
- Develop a comprehensive framework for the timely evaluation and management of significant post-market signals.¹²

Furthermore, the past two years have witnessed the inauguration of international PMCF consortia such as:

- International Consortium of Orthopaedic Registries (ICOR) in 2011; and
- International Consortium of Cardiovascular Registries (ICCR) in 2013.

This market-wide shift, aims at providing more transparency for the medical community and patients; importantly, working toward a better guarantee of long-term safety and performance.

In addition to the broad commitment to improve delivery on the promise of long-term safety and efficacy, industry trends have contributed to the need for a greater emphasis on PMCF. With a global economy that is recovering from the recent downturn, medical device manufacturers faced with changes to the regulations and associated costs have made a strong commitment to investing in new technology and R&D in order to overcome financial challenges. Innovation means more efficient and economical devices, but it also presents manufacturing and implementation including regulatory compliance, challenges.

The continued development of highly innovative medical devices, while positive for the industry, patients, and the global community, creates an even greater need for clinical data (especially in the post-market phase). Governments, NBs, and manufacturers alike are realizing the importance of this long-term clinical data not only for the well-being of patients, but also to continue the development and manufacture of innovative, effective, affordable, and life-changing medical devices.

With growing challenges and demands for innovation, manufacturers will benefit from the support of NBs who, through their feedback and knowledge of MDD requirements, will help balance the need for long-term clinical data with innovation.

Final thoughts – Translating the value of clinical data beyond compliance

A robust PMS program provides:

- real-world experience with a broad spectrum of physicians and patients, outside the confines of pre-market trial(s);
- early warning of a problem;
 - reveals low frequency events,
 - long-term performance of device,
 - monitors effect of design changes,
- early corrective action;
- compliance with relevant legislation;
- additional value beyond compliance (e.g. marketing, legal).

The value of clinical data extends beyond compliance or identifying and eliminating any residual risk to patients. Long-term clinical data can also translate into economic value for medical device manufacturers; having robust clinical data for a medical device is an excellent marketing tool that can improve sales and payer reimbursements and can be used to support defense of product liability claims.

Moreover, with a global legislative shift that is directing the need for a particular emphasis on PMCF requirements, as well as the benefits of selecting an accredited, experienced in key medical devices technology areas, and well-resourced NB in the assessment of such plans, manufacturers, physicians, and patients stand to benefit greatly from strict compliance to EU ERs and a long-term commitment to PMS.

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Published white papers

The Proposed EU Regulations for Medical and In Vitro Diagnostic Devices – An Overview of the Likely Outcomes and the Consequences for the Market – Gert Bos and Erik Vollebregt

Generating Clinical Evaluation Reports – A Guide to Effectively Analysing Medical Device Safety and Performance – Hassan Achakri, Peter Fennema and Ito Udofia

Forthcoming papers

What You Need to Know About the FDA's UDI System Final Rule (working title), Jay Crowley and Amy Fowler (July, 2014)

The Digital Patient (working title), Kristin Bayer, Laura Mitchell and Sharmila Gardner (August, 2014)

Usability Engineering (working title), Bob North (September, 2014)

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