Medical device software: Regulations and Standards

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Introduction

Medical Device Software is software that has been developed for the purpose of being incorporated into a physical medical device or that is intended for use as a medical device in its own right to be run on a non-medical hardware platform. The latter is known as Software as a Medical Device (SaMD) sometimes called ‘stand-alone medical device software’.

If medical device software is produced for use on the European market it must be CE marked in accordance with the Medical Devices Directive 93/42/EEC as amended.↑ In the USA, pre-market approval must be sought from the FDA (2015) (Vogel 2010).

This presentation will concentrate on the European regulatory situation.

Method – Regulations

The definition of a medical device is given in Article 1.2(a) of the Medical Devices Directive (MDD). It clearly includes software that is intended by the manufacturer for the purpose of diagnosis, prevention, monitoring treatment or alleviation of disease or compensation of an injury or handicap. The intended by the manufacturer phrase is important because if the intention is a research one, even if patients are involved, then the device is not formally a medical device and the Directive does not apply. However, if the purpose of the research is to investigate the safety or effectiveness of the device with a view to possibly placing it on the market if successful, then other parts of the Directive do apply and application to the Competent Authority in your EU nation is required.

If the software device is not placed on the market i.e. is used only in-house, then again the Directive does not apply. A recent article by Cosgriff et al. (2016) is very useful.

Method – Standards

If software is being written to be placed on the EU market, it must meet the Essential Requirements given in Annex I of the MDD. Even if formal regulation does not apply, there is a moral, ethical and legal duty of care to apply ‘best practice’ so that risks are reduced to an acceptably low level. Certain formal Standards are cited by the European Commission as giving a ‘presumption of conformity’ to relevant Essential Requirements and these Standards represent the consensus of current best practice. They should therefore be used whether the software device has to meet the MDD or not.

↑ A consolidated text of MDD 93/42/EEC which takes into account all of the revisions up to and including Directive 2007/47/EC is available from:-
The most relevant Standard is IEC 62304:2006+A1:2015, also available as BS EN 62304:2006+A1:2015. A series of guidance documents for medical device software is in development by IEC in the 80002 series. IEC/TR 80002-1 and IEC/TR 80002-3 are published and IEC/TR 80002-2 is in preparation. IEC/TR 80002-1 refers out to ISO 14971 on risk management, and this is also a very important Standard to be considered. However in a European context, Annex ZA in the EN version should be consulted. Finally, IEC 62366-1 on usability engineering is also relevant and important.

In the UK, the MHRA has very recently updated its guidance on medical device software as part of its guidance for manufacturers on clinical investigations. (MHRA 2016).

Discussion & Conclusions

The MDD is to be replaced by an EU Regulation which has a different legal status. This will introduce some ‘light touch’ regulation of both in-house manufactured devices and devices made for non-regulatory research purposes. From about late 2019 these will be compulsory.

Standards and References


IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices

IEC TR 80002-1:2009 Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software

ISO TR 80002-2: Medical device software – Part 2: Validation of software for regulated processes (in draft)


ISO 14971:2007 Medical devices – Application of risk management to medical devices


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