DITTA Contribution on Software as a Medical Device

at the occasion of the IMDRF meetings in San Francisco, 25-27 March 2014

DITTA congratulates the IMDRF for promoting the dialogue of regulators and industry and presenting a common foundation for a regulatory framework for Software as a Medical Device (SaMD). DITTA strongly supports the global convergence of all regulatory frameworks for medical devices, and we appreciate the opportunity to be involved in this IMDRF Work Item since its launch.

We would like to take the opportunity of this Forum to articulate our key messages:

1) **Qualification of SaMD: Continue clarifying how the SaMD definition applies in practice**
2) **Risk stratification: Protect innovation by continuing to pursue a framework tailored to the essentially indirect risks that SaMD can pose**
3) **Controls: Consider leveraging industry's best practices of design, rather than relying exclusively on traditional verification and validation requirements**

Qualification of Software as a Medical Device (SaMD)

Many authorities around the world regulate (or plan to do so) software-only products that are placed on the market with a medical purpose. The description of when software is considered a 'medical device in its own right' varies significantly across the IMDRF jurisdictions.

DITTA appreciates that IMDRF has recently provided more clarity on the SaMD definition, replacing the initial term of 'standalone software' to indicate software that does not require any specific hardware or network to be qualified as a medical device. We strongly recommend that this new clarification is also introduced into a future revision of the Phase I (Key Definitions) document.

SaMD Types / Risk Stratification

Beyond the SaMD qualification aspects, the various controls imposed on SaMD are currently different and also changing in most parts of the world. The IMDRF SaMD Working Group is creating an opportunity for mutual learning, and working to bring regulators to the table and have them align on global terms, qualification methods and sets of controls for regulations.

The consideration of the various risks of software usage is the common basis for different controls in regulations. The use as intended by the SaMD manufacturer is a global key starting point to evaluate the risk.

The current SaMD framework works like this: Based on the manufacturer's intended use, the foreseeable usage scenarios are evaluated with respect to risk for patients and – lacking a real metric – risk-based 'types' of software. Risks introduced via the usage scenarios are then assigned respective sets of appropriate controls. This approach is specific to SaMD due to the nature of the product and its use.

For the direct effects of software that drives or controls medical devices, risks are obvious and their management well defined. However, the value of software and SaMD in particular, is the user's ability to integrate them into a clinical environment, with an increasing indirect – yet foreseeable – risk for patients that can be fatal and must be examined via the proposed IMDRF framework, too. The indirect impact is inherent to the nature of the product, as it provides data for informed decision making or influences behavior. This differs from traditional medical devices based on hardware.

This matter is certainly new territory for us. For sure it is hard to determine the "indirect, but foreseeable" consequences of a SaMD or an integrated environment with a SaMD. As all this work happens in a traditional medical device world, that places a special emphasis on the potential adverse side-effects of a device or its function(s) and focuses less on the outcomes, an opportunity for innovation may be missed. As a result, many factors of SaMD usage that may influence the SaMD's (indirect) harmful consequences are being considered in a risk-based software stratification schema.

We appreciate the fact that IMDRF is exploring dedicated approaches to establish a meaningful yet risk-based regulatory framework that is adequate to the particular type of product and does not pursue the one size fits all approach. If the existing regulatory framework for traditional medical devices would be applied to SaMD, this would not address the risk profile and it would affect innovation and better outcomes in healthcare.

The IMDRF SaMD framework does not yet require a structured "form" for the Intended Use. However, when the underlying list of risk-relevant questions becomes stable, it can be expected that regulators may ask for something that is (in the pharmaceutical world) well-known as a 'structured submission.'

Controls for SaMD Types

The controls in existing regulations mainly target registration, verification and validation and focus less on how correct and reliable software is being specified and constructed.

Therefore we will see verification and validation requirements as suggested controls in the near future but hopefully some shift towards best industry practices of design, e.g. in the fields of architecture, modelling, generating artifacts, and agile methods.

DITTA is a global association of manufacturers that represent medical imaging, radiation therapy, healthcare IT, electromedical and radiopharmaceutical manufacturers. Member companies manufacture: medical x-ray equipment; computed tomography (CT) scanners; ultrasound; nuclear imaging; radiation therapy equipment; magnetic resonance imaging (MRI); imaging information systems; medical software and health IT; and radiopharmaceuticals.

DITTA's membership currently includes ABIMED (Brazil), CAMDI (China), COCIR (Europe), IMEDA (Russia), ITAC (Canada), JIRA (Japan), KMDICA (Korea), MEDEC (Canada), MITA (United States) and THAIMED (Thailand).

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