Summary Report NET WG: mHealth technology example regulatory analysis under MDR

Endorsed by NET WG on 24 November 2017

Introduction

The new Regulations on Medical Devices (MDR) and In Vitro Diagnostic Medical Devices (IVDR) published on 5th May 2017 contain a number of provisions that reflect the scientific and technological progress in information and communication technologies (ICT). The NET WG worked on ICT applications in the past, and this work was fed into the Commission's considerations[1], contributing to the legislative proposals on medical devices presented by the European Commission in September 2012 and during the subsequent negotiation process[2].

During the past years, the NET WG has followed several ICT applications that qualify as novel devices[3], in particular from the emerging field of mobile health (mHealth). A representative example of this technology was chosen to present the regulatory challenges of this technology to the current medical device legal framework and how these are addressed by the new Regulations.

The technology herein presented is a **mHealth** system intended[4] to measure and monitor several physiological parameters, such as temperature, heart rate, pulse oximetry and blood pressure (the Scanadu Scout[5]). A small **wearable device**, combining multiple electrodes and an infrared sensor, is used for the scan of the different above mentioned parameters from a gentle touch on the forehead and sends the data via Bluetooth to the user's **smartphone**. Thus, an **app** is also available as part of the system. The data collected can also be transmitted to the doctor. Just before endorsing this analysis in the plenary NET WG, the information on the internet pages of the company were checked, and it was found that only the homepage was available at that time. However, from a recent publication[6] the Scout investigational device seems to be discontinued and a final report was expected to be published during 2017 with the data collected from the 18-month study survey. This seems also to be in line with clinicaltrials.gov, where it is indicated that the study is ongoing but not recruiting participants.

Although the current status of the product and the company are not entirely clear, the NET WG considered it appropriate to present the results from the regulatory analysis of the indicated example, as it can constitute useful information for similar technologies to be taken into consideration under the implementation process of the new regulations.

---

[1] 2011 - NET "wish list"- contribution for the recast of medical device directives.

[2] 2013 – Definitions of compatibility and interoperability submitted to MDEG meeting (09july2013)

[3] According to definition of "novel device" submitted to MDEG meeting (09july2013)

[4] Indications for use: "The Scanadu Scout™ is intended for use by adults…for the purpose of enabling adults to manage their health. It is not intended for diagnostic purposes.

[5] The Scanadu Scout™ is currently an investigational device (US).

[6] https://techcrunch.com/2016/12/13/fda-orders-scanadu-to-shut-down-support-for-its-scout-device-and-customers-are-mad/

Results and Conclusions

The assessment of this mHealth system was based on publicly available information and has followed a TT-matrix methodology, defined at the NET WG, for the identification and assessment of new and emerging technologies. As a result of this exercise, several challenges to the current directives were identified (see the attached Table) and the most relevant provisions on how they are addressed in the new regulations as well. However, this should not be considered an exhaustive list.

The following aspects were considered to be critical issues for this kind of technology:

- The fact that this is at the borderline of a medical device and a consumer product, intended for different kinds of users, with different kinds of skills and vulnerabilities. It is wearable and easy to access. Note: The intended use should be clear whether it is for wellness, health monitoring or diagnostic purposes and with regard to required action on the resulting information (users should be able to know what the data mean and how to act on it)
- The technology behind each part of the system (sensor, software and hardware) and the interaction among them. The quality of the data generated by such a system. The need of adequate clinical evidence. Privacy and security associated to the use of the software.
  Note 1: Hardware/mobile computing platform features might be especially critical if this platform is also used for data capturing; the system partly relies on the user's own smart phone.
  Note 2: Sensors technology might be especially critical in the case of implantable/ingestible.
  Note 3: Reliability and safety shall be clear for this kind of technology. Extensive validation data for the whole system have to be available, answering the need for formal validation of the intended use and clinical claims as well as usability.
  Note 4: Adequate user (patient/consumer) guidance, and regulatory oversight shall be mandatory
- Possible communication with Electronic Health Records (EHR) and recommended/prescribed by health professionals as part of a treatment/monitoring process

These aspects should be taken into account in the risk management process and be aligned and reflected in the clinical evaluation for this kind of technology.

Despite the improvements introduced by the MDR, in particular with regard to ICT, it is expected that relevant safety and performance requirements, that are general in nature, would require further guidance in order to facilitate uniform application. Therefore, the NET WG recommends:

- To share this example with the Software WG and CIE WG given the challenges with regard to software and clinical evaluation/investigation, and with the Borderline & Classification WG.
- In liaison with the other WGs, to consider the need for the development of specific guidance addressing the indicated critical aspects for this kind of technology.

Moreover, other International and European initiatives were found to be contributing to worldwide harmonization in the MD field and as an additional improvement of privacy, safety (including security), usability and accessibility of MD and also quality of borderline software (MD/wellness).

Challenges to MD	MDR provisions	Other European and International initiatives
Medical/"Consumer" product / Intended use • for self-monitoring/diagnostic; • Tenuous borderline between medical (diagnostic/monitoring) and non-medical (lifestyle and wellbeing) purposes • Users: laypersons/healthcare professionals (Impact on classification) • Short lifecycle for the app: manufacturers Introduce frequent changes to their software (User/Patient may not timely install a software update to fix critical issues) - health and digital literacy) – • traceability of different versions – post-market surveillance (Field Safety Notice/ Recall/CAPA) • IFU /labelling (paper format vs electronic format in device user interface or website) • Health and digital literacy	*Intended use:* • *MD definition*: art. 2, point 1. (…medical purpose…prediction and prognosis); • Direct diagnosis definition, Annex VIII, point 3.7. • "…diagnosis and monitoring…", definitions specific to classification rules classification rule, Chapter I on point 2.5 of Annex VIII *Qualification/classification of the software/App as a MD* • "…software intended for lifestyle and well-being purposes are not MD… The qualification of software…is independent of its location or type of interconnection…"(Recitals 19 in MDR) • active device intended to *monitor*/diagnosis: (Rule 10) of Annex VIII); *Instructions for use (paper vs electronic format)* Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent and ***only*** under the conditions set out in Commission Regulation (EU) No 207/2012 or in any subsequent implementing rules adopted pursuant to this regulation (Annex I, point 23.1 f) *UDI requirements also for MD software* (Annex VI, part C, point 6.5) *Information to the user* Transparency and better **adequate access to** information**, appropriately presented for the intended user,** are essential **in the public interest, to protect public health,** to empower patients and healthcare professionals and to enable them to make informed decisions, to provide a sound basis for regulatory decision-making and to build confidence in the regulatory system. (Recital 35)	**IMDRF** • "Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations"; • "Software as a Medical Device: Possible - Framework for" • "Guidance for the Clinical Evaluation and Evidence for Software as a Medical Device (SaMD) - current work item **FDA** • General Wellness: Policy for Low Risk Devices • Guidelines for post market management of cybersecurity risks in medical devices **DGCNECT** • **Report of the** *Working group on mHealth* - "EU guidelines on assessment of the reliability of mobile health applications"
Usability (for elderly people and for those with disabilities -)	*Usability:* "Data gathered by the manufacturer's post-market surveillance system shall in particular be used:...for the	

	identification of possibilities to improve the *usability,* performance and safety of the device*;…"Article 83, point 3(f)*	• mHealth Code of Conduct - how to guide for privacy law compliance) • • *Usability and accessibility* - Proposal for a Directive on the accessibility of the public sector bodies' websites(people with disabilities) • *Safety aspects* - Public consultation on the safety of apps and other non-embedded software • The Directive on security of network and information systems (NIS) . **General Data Protection Regulation**
Clinical relevance /Clinical evidence "… is now conducting a completely mobile-based trial analyzing the impact of the Scanadu Scout[7] ……. The aim of the study is to understand how the device modifies health behaviours in participants and to evaluate the ease of use and acceptance of the technology…" "The sensor collects vital signs data in about 10 seconds then sends it to its smartphone app over a Bluetooth connection. Once in the app, the data can be viewed by the study participant and collected by researchers." "The traditionally conducted clinical trial model requires increasing amounts of time, cost, and resources for both sponsors and sites...".[8] Note: This kind of technology could impose a safety risk for their users if used for medical (diagnostic) purposes. Thus a reliability of the measurements of the vital signs shall be proved according to principles of Clinical Evaluation pursuant to EU legal medical device framework)	*Clinical evaluation and clinical investigations* The reinforcement on the rules on clinical data and the reinforced requirements for manufacturers to collect data about the real-life use of their devices. • General requirements are foreseen for clinical evaluation/investigation (Chapter VI, articles 61-82) • Possible impact on how to conduct CI studies - also if considered the fulfilment of requirements of harmonized standard EN ISO 14155 "Clinical investigation of medical devices for human subjects – good clinical practice" which are applied during clinical investigation planning and execution.	
Quality of the data delivered by the system – Sensor/Software. • Generated data/ content (involves data capturing via sensors) – captured data needs to be accurate, reproducible, comparable, relevant in line with the intended use etc. • Interpretation of data (involves data processing) – correct algorithms. Scanadu Scout "…has not yet been clinically tested for accuracy compared to devices taking one or more similar measurements. Its performance characteristics have not yet been established…"[4].	*Software* • Repeatability, reliability and performance according to the intended use (Annex I, 17.1) • the principles of development life cycle, risk management, verification and validation (Annex I, 17.2) Note: Reliability of the algorithms used shall be tested and validated clinically	
interaction hardware-software - the use of software in combination with mobile computing platforms • Medical device software might behave differently when deployed to different hardware platforms.	*Software … intended to be used in combination with mobile computing platforms* *(*Annex I, point 17.3)*Hardware (*Annex I, point 17.5)	
Data Transmission/telemetry function • Data transmission failure, problem for identification of patient during data transmission to doctor,..);	*Data Transmission/telemetry function* New requirements on the Annex I, point 14.2.b), and f)	

[7] http://crbtech.in/Clinical-Research/medical-research-rebuilt-retooled-rebooted/ - The study is listed at https://clinicaltrials.gov/ct2/show/NCT02134145

[8] http://thehealthcareblog.com/blog/2015/09/03/clinical-research-rebooted/ and https://www.scanadu.com/blog/clinical-research-rebuilt-retooled-and-rebooted

• Limitations due to missing/lack of wireless connections eg. Wi-Fi break down, travelling, countryside etc.		
Interoperability (with EHR)	*Interoperability* New requirement (Annex I, point 14.5) and definition (art 2, point(26))	
Privacy/Security • Secure transmission and storage of data. • External hacking of software	*Privacy/Security* IT security measures, including protection against unauthorised access (Annex I, point 17.2 and point 17.3)	