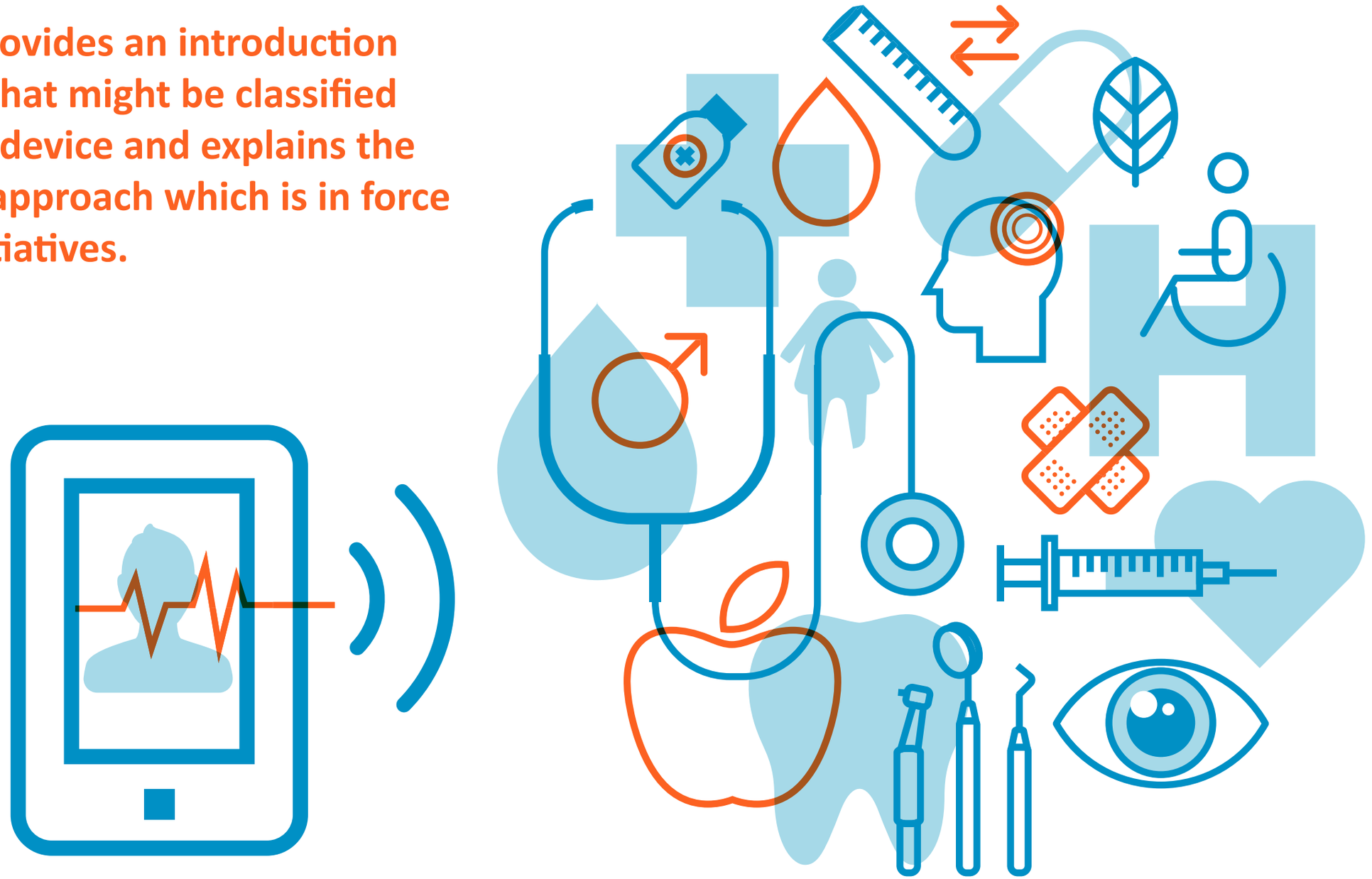
Medical Software Guide V3.0

This guide provides an introduction to software that might be classified as a medical device and explains the governance approach which is in force for all PH initiatives.



Integrated Multi-Channel Marketing

Introduction

The governance approach that can be found in this document was endorsed by the Global Product Development Committee in December 2015, is valid for all PH initiatives, and was solidified in the SOP “Approval of Material intended for Communication with External Persons” (BHC-RD-SOP-041).

The guide provides basic information on how Medical Software is regulated and how it can be categorized. In-depth information can be accessed in the respective guides for the different regulations. The guidance covers stand-alone software (also known as software as a medical device) but not software that is part of an existing medical device, as this is seen to be part of the device (hardware).[1]

[1] *According to European Medical Device Directive (MDD – 93/42/EEC), covered in more detail in the “Medical Software EU Regulations v2.0” Guide*

Key Points for Medical Software

Stand-alone Software

Software with a medical purpose which at the time of it being placed onto the market is not incorporated into a medical device.

Intended Purpose / Intended Use

Regulation of medical devices is limited by the intended purpose as defined by the manufacturer. This will include claims given in promotional materials for the device, e.g. brochures and webpages.

Medical Purpose

Software that has a medical purpose could be a medical device. A medical device is defined by the Global Harmonization Task Force (GHTF/SG1/N71:2012) as:

"… software … intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- control of conception ...”

Please take a look at the Medical Software Assessment Template for further support.

Software Applications & Mobile Apps

If the software meets the definition of a medical device, it will be regulated as a medical device.

According to European Medical Device Directive (MDD – 93/42/EEC), covered in more detail in the “Medical Software EU Regulations v2.0” Guide

The words and phrases listed right are all likely to contribute to a determination by a regulatory body that the app they were associated with is a medical device:

- amplify
- analysis
- interpret
- alarms
- calculates
- controls
- converts
- detects
- diagnose
- measures
- monitors or checks

This includes software providing personalized guidance based on information it has about a specific individual and makes use of data entered by him/her, provided by point of care devices or obtained via health records.

- Apps acting as accessories to medical devices such as in the measurement of temperature, heart rate, blood pressure, blood sugars or other patient-specific medical data could be a medical device.

- Software that monitors a patient and collects information entered by the user, measured automatically by the app or collected by a point of care device may qualify as a medical device if the output affects the treatment of an individual.

- Software that provides general information but does not provide personalised advice, although it may be targeted to a particular user group, is unlikely to be considered a medical device.

- Software that is used to book an appointment, request a prescription or have a virtual consultation is also unlikely to be considered a medical device if it only has an administrative function.

Some decision support software may not be considered to be a medical device if it exists only to provide information enabling a health-care professional to make a clinical decision as they ultimately rely on their knowledge.

However, if the software or app performs a calculation or patient-specific analysis or interprets or interpolates data and provides patient-specific diagnosis, or treatment recommendations, then this software may be considered a medical device.

General requirements

Manufacturers of a Medical Software are expected to undertake appropriate controls and to integrate appropriate risk management processes for mitigating risk to an acceptable level and for achieving the intended performance.

Generally, controls that are applicable for a medical device may also be considered by the manufacturer for applicability for a specific Medical Software. Medical Software must be developed in a safe and effective manner, using risk and quality management principles. The recommended controls for all types of Medical Software are:

- a quality management system (QMS), including
- a system for post-market surveillance
- and technical documentation

Regulations differ e.g. for EU, US and Canada (please see details in the respective guides).

PH Governance for Medical Software

Medical Affairs is the driving force to identify medical software (see BHC-RD-SOP41).

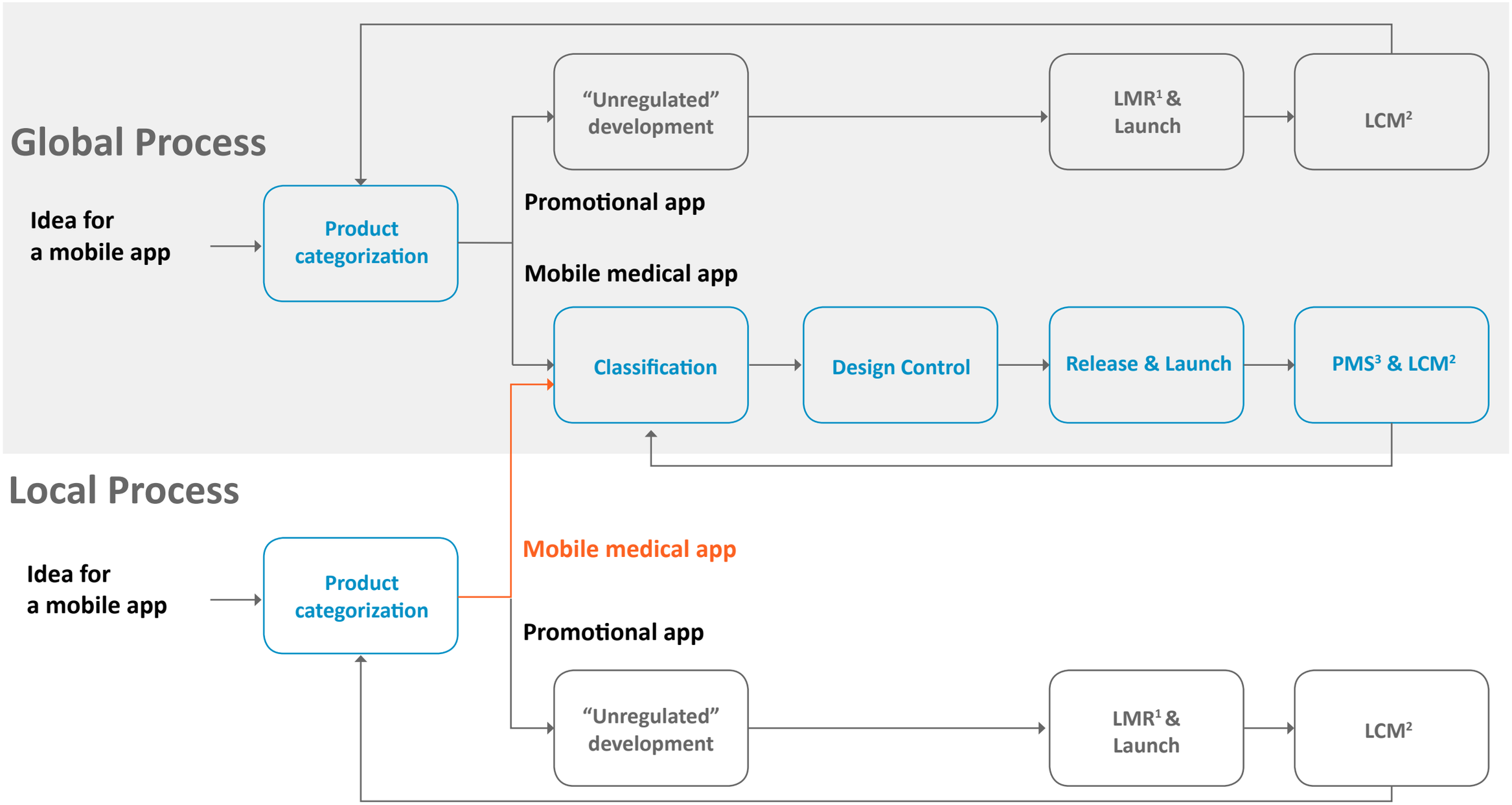
Early identification of medical software is key to achieve a general and timely project approval through the Global Product Development Committee (GPDC) and to apply the global medical device development process.

Due to regulatory requirements, the development as well the maintenance of medical software is quite costly and needs appropriate business case justification.

As soon as it is clear that medical software will be developed Chemical and Pharmaceutical Development will support and lead the project (contact Head of CPD Special Technologies & Application Systems).

CPD will guide the project through the global medical device development process, which starts with an approval of the medical software through the GPDC (see image 1 and 2).

All Medical Software to be Governed by Global Process



[1] LMR = Legal Medical Regulatory Review; [2] LCM = Lifecycle Management; [3] PMS = Post-market surveillance

Medical Device Development Process and Governance

Device Development Process (AS Process)

Decision body:		GPDC	MDRC	MDRC	MDRC	GPDC	PS Mgmt.
PF	→	AS1	AS2	AS3	AS4	AS5	AS6
Generation of product ideas		Start of project	Approval of Product Specification	Approval of Technical Design	Approval of Manufacturing-Design	Approval for Product Submission	Completion of Design Transfer

Governance

Global Program Team

Device Development Team

- **Chem. Pharm. Dev. (lead)**
- Marketing
- Global Regulatory Affairs / Legal
- Product Supply
- Pharmacovigilance
- Medical Affairs and others[1]

[1] *E.g. Medical Affairs, Clinical Development, Legal, Abbreviations: CPD = Chemical and Pharmaceutical Development, GPDC = Global Product Development Committee, MDRC = Medical Device Review Committee, PS = Product Supply*

In case of borderline decisions, the Medical Software Expert Committee, led by RA (Head of CMC Management, BPH-GD-RA-GROC-GC-MCM, contact *mse.committee@bayer.com*) will help to clarify the product categorization.

Please note that also updates of software need to be reviewed and approved in light of a possibly new/changed product categorization or a necessary new CE Certification.

Medical Affairs can only approve digital content in the Approval Work Bench (AWB) once they have conducted the medical software assessment and in case of medical software:

- once the device development process (AS process) had been completed and the release for submission was granted by the Global Product Development Committee (GPDC).

Please note that mobile medical apps (also in English language) need an LMR approval in all countries where the distribution of the app will take place. The BBS global mobility group is responsible for the publishing process in e.g. Apple's App Store and Google's Play Store and thus will only allow publishing in countries were the app has been LMR approved.

Important

Bayer Software that, from a regulatory perspective, is defined as a medical device has to follow regulatory requirements. Otherwise, severe consequences can be expected:

- Violation of applicable laws or regulations could result in penalties and/or
- Humans could be harmed
- Company/product image could be severely damaged
- Product sales could decrease
- Marketing approval revoked

Identifying Medical Software

We recommend that the project owner and Medical Affairs proceed with the assessment according to the “medical software assessment process” (see image 3). The respective qualification templates that are meeting applicable regulatory requirements (EU, US or Canada) need to be used (see Medical_Software_Assessment_Templates.docx).

For countries not covered by the EU/US regulations, a country specific evaluation should be performed. However, as many countries follow either EU or US regulations, a preliminary assessment based on the guiding country/region should be appropriate to classify software as medical or not.

In case of borderline decisions contact the Medical Software Expert Committee (*MSE.Committee@bayer.com*).

Process Step	Task	Owner	Review	Support
Does my software qualify as a medical device?	Use „Software Description“ template for EU ↓ Use „Qualification as Medical Device“ template for EU,US or CA	Project Owner, e.g. Marketing Manager	Medical Affairs (and Legal and Reg. Affairs if required)	Expert committee (lead GRA) to support borderline decisions
Next	NO: Develop software as usuallly YES: Contact GCPD. Start AS process	Project Owner, e.g. Marketing Manager		

Regulatory Differences in US and EU

The following presentation covers nuances and requirements of the US and EU regulatory environments.

For some medical software that may meet the definition of medical device the FDA intends to exercise enforcement discretion.

These mobile apps may be intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease. Even though these medical software may meet the definition of medical device, the FDA intends to exercise enforcement discretion as they pose lower risk to the public.

The EU regulation today does not exercise enforcement discretion which results in different regulatory requirements.

The presentation details the topic and reflects Bayer’s perspective based on examples.

Enforcement Discretion

FDA vs. EU Regulation

U.S. Department of Health and Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA Enforcement Discretion

FDA Requirements for Enforcement Discretion

- Help patients/users self-manage their disease or condition without providing specific treatment suggestions
- Provide patients with simple tools to organize and track their health information
- Provide easy access to information related to health conditions or treatments
- Help patients document, show or communicate potential medical conditions to health care providers
- Automate simple tasks for health care providers or
- Enable patients or providers to interact with Personal Health Records (PHR) or Electronic Health Record (EHR) systems.

FDA's mobile medical app policy does not apply to mobile apps that function as an electronic health record (EHR) system or personal health record system.

Medical Device Directive 93/42/EEC

EU Requirements “to be or not to be”

Software have to fulfil a Medical Purpose

Software that has a medical purpose could be a medical device.

‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- control of conception

Software Applications (apps)

The words and phrases listed below are all likely to contribute to a determination by a regulatory body that the app they were associated with is a medical device:

- amplify
- interpret
- analysis
- controls
- diagnose
- alarms
- measures
- monitors
- calculates
- checks
- converts
- detects

Apps which might be a medical device

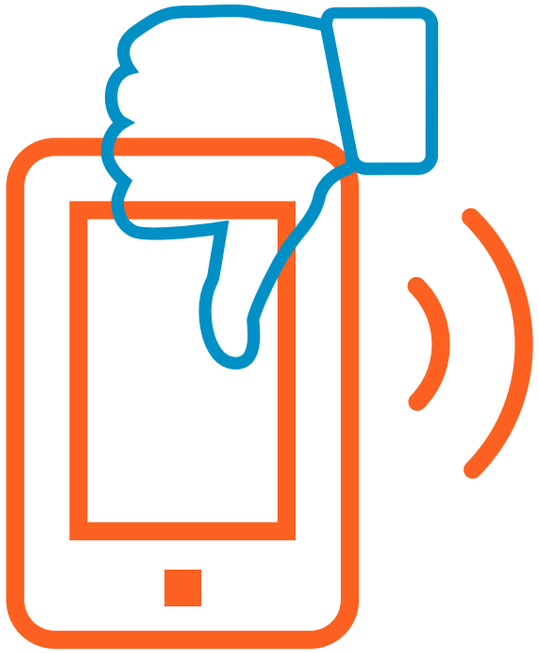
- …providing personalized guidance based on personalized specific information (data entered manual, provided by point of care devices or obtained via health records)

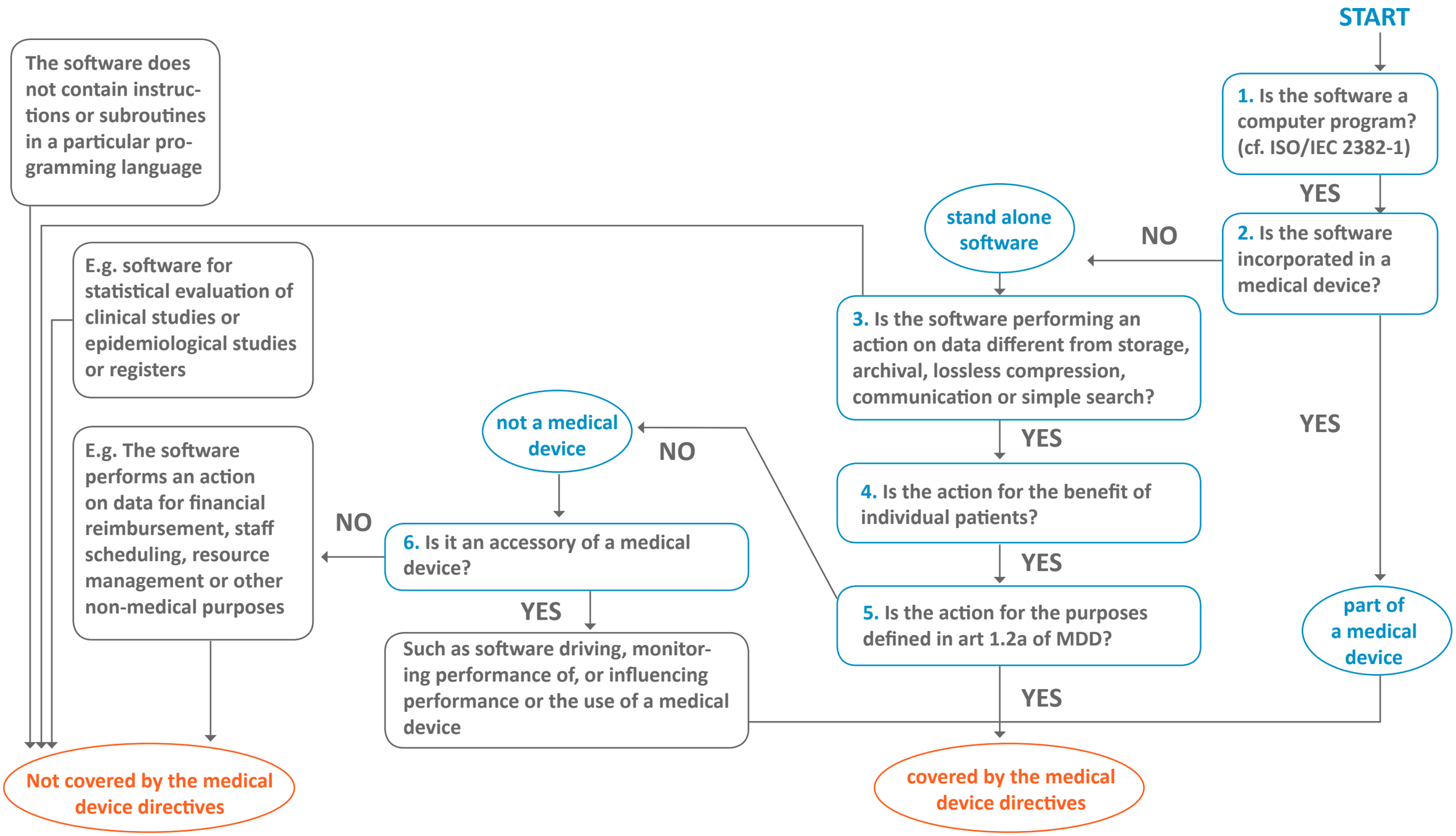
- …accessories to medical devices (measurement of temperature, heart rate, blood pressure and blood sugars)

- …monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the t reatment of an individual

Apps which might not be a medical device

- …providing general information, no providing of personalised advice
- …communication with healthcare providers (booking appointments, request prescriptions, virtual consultation…)




START
1. Is the software a computer program? (cf. ISO/IEC 2382-1)
YES
2. Is the software incorporated in a medical device?
NO
stand alone software
3. Is the software performing an action on data different from storage, archival, lossless compression, communication or simple search?
YES
4. Is the action for the benefit of individual patients?
YES
5. Is the action for the purposes defined in art 1.2a of MDD?
YES
covered by the medical device directives
YES
part of a medical device
NO
not a medical device
6. Is it an accessory of a medical device?
YES
Such as software driving, monitoring performance of, or influencing performance or the use of a medical device
NO
E.g. The software performs an action on data for financial reimbursement, staff scheduling, resource management or other non-medical purposes
Not covered by the medical device directives
The software does not contain instructions or subroutines in a particular programming language
E.g. software for statistical evaluation of clinical studies or epidemiological studies or registers

Apps which might not be a medical device

3. Is the software performing an action on data different from storage, archival, lossless compression, communication or simple search?

Q3 if the software does not perform an action on data, or performs an action limited to storage, archival, communication, 'simple search' or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device.

- 'Simple search' refers to the retrieval of records by matching record metadata against record search criteria, e.g. library functions. Simple search does not include software which provides interpretative search results, e.g. to identify medical findings in health records or on medical images.

Apps which might not be a medical device

3. Is the software performing an action on data different from storage, archival, lossless compression, communication or simple search?

Q3 if the software does not perform an action on data, or performs an action limited to storage, archival, communication, ‘simple search’ or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device.

- Altering the representation of data for embellishment purposes does not make the software a medical device. In other cases, including where the software alters the representation of data for a medical purpose, it could be a medical device.
If the create or modify medical, If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by the healthcare professionals

Apps which might not be a medical device

3. Is the software performing an action on data different from storage, archival, lossless compression, communication or simple search?

Note: the display of images usually involves alterations to the representation due to standard image processing techniques

- Alterations may include reconstruction, lossy compression, filtering, pattern recognition, modelling, interpolation, transformation, classification (e.g. scoring of tumors against specific criteria), segmentation, registration (e.g. mapping a data set to a model or atlas or to another data set, e.g. registering an MRI image on a CT image), calculations, quantification, qualification (e.g. comparison of data against references), rendering, visualisation, interpretation, etc..

Apps which might not be a medical device

4. Is the action for the benefit of individual patients?

Q4 an example of software for the benefit of individual patients is software intended to be used for the evaluation of patient data to support or influence the medical care provided to that patient.

- Examples of software which are not considered as being for the benefit of individual patients are those which aggregate population data, provide generic diagnostic or treatment pathways, scientific literature, medical atlases, models and templates as well as software for epidemiologic studies or registers.

Apps which might not be a medical device

5. Is the action for the purposes defined in art 1.2a of MDD?

Q5 aif the manufacturer specifically intends the software to be used for any of the purposes listed in Article 1(2)a of Directive 93/42/EEC, then the software shall be qualified as a medical device.

However, if only a non-medical purpose is intended by the manufacturer, such as invoicing or staff planning, it is not a medical device.

Note: A task such as e-mailing, web or voice messaging, data parsing, word processing, and back-up is by itself not considered as being a medical purpose, according to Directive 93/42/EEC.

FDA examples for enforcement discretion

EU ~ Regulated as Medical Device yes / no

1. Mobile apps that help patients with diagnosed psychiatric conditions (e.g., post-traumatic stress disorder, depression, anxiety, obsessive compulsive disorder) maintain their behavioral coping skills by providing a “Skill of the Day” behavioral technique or audio messages that the user can access when experiencing increased anxiety; …personalized guidance based on personalized specific information …providing general information, no providing of personalised advice

2. Mobile apps that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women; …providing general information, no providing of personalized advice

3. Mobile apps that use GPS location information to alert asthmatics of environmental conditions that may cause asthma symptoms or alert an addiction patient (substance abusers) when near a pre-identified, high-risk location; …diagnosis, prevention, monitoring, treatment or alleviation of disease

EU ~ Regulated as Medical Device yes / no

4. Mobile apps that use video and video games to motivate patients to do their physical therapy exercises at home; …providing general information, no providing of personalised advice

5. Mobile apps that prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature and a summary of what type of interaction was reported; …'Simple search' refers to the retrieval of records by matching record metadata against record search criteria

6. Mobile apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks; …monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual

7. Mobile apps that prompt the user to manually enter symptomatic, behavioral or environmental information, the specifics of which are pre-defined by a health care provider, and store the information for

EU ~ Regulated as Medical Device yes / no

later review;…monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual

8. Mobile apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling and preventive recommendations from well-known and established authorities;
…personalized guidance based on personalized specific information
…simple search does not include software which provides interpretative search results

9. Mobile apps that use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care provider; …monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual
10. Mobile apps that guide a user through a questionnaire of signs and symptoms to provide a recommendation for the type

EU ~ Regulated as Medical Device yes / no

of health care facility most appropriate to their needs; …monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual

11. Mobile apps that record the clinical conversation a clinician has with a patient and sends it (or a link) to the patient to access after the visit; … if the software does not perform an action on data, or performs an action limited to storage, archival, communication, 'simple search' or lossless compression

12. Mobile apps that are intended to allow a user to initiate a pre-specified nurse call or emergency call using broadband or cellular phone technology; … A task such as e-mailing, web or voice messaging, data parsing, word processing, and back-up is by itself not considered as being a medical purpose ???

13. Mobile apps that enable a patient or caregiver to create and send an alert or general emergency notification to first

EU ~ Regulated as Medical Device yes / no

responders; … A task such as e-mailing, web or voice messaging, data parsing, word processing, and back-up is by itself not considered as being a medical purpose …communication with healthcare providers (booking appointments, request prescriptions, virtual consultation…)

14. Mobile apps that keep track of medications and provide user-configured reminders for improved medication adherence; … pill reminder devices are not considered as medical devices according to MHRA guidance “Borderline with medical devices”

15. Mobile apps that provide patients a portal into their own health information, such as access to information captured during a previous clinical visit or historical trending and comparison of vital signs (e.g., body temperature, heart rate, blood pressure, or respiratory rate); does …not perform an action on data, or performs an action limited to storage, archival, communication, ‘simple search’ or lossless compression

16. Mobile apps that aggregate and display trends in personal health incidents (e.g., hospitalization rates or alert notification

EU ~ Regulated as Medical Device yes / no

rates); … alters the representation of data for a medical purpose, it could be a medical device. If the create or modify medical, If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by the healthcare professionals

17. Mobile apps that allow a user to collect (electronically or manually entered) blood pressure data and share this data through e-mail, track and trend it, or upload it to a personal or electronic health record; …monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual

18. Mobile apps that provide oral health reminders or tracking tools for users with gum disease; …monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual

19. Mobile apps that provide prediabetes patients with guidance or tools to help them develop better eating habits or increase physical activity; …providing general information, no providing of personalised advice

EU ~ Regulated as Medical Device yes / no

20. Mobile apps that display, at opportune times, images or other messages for a substance abuser who wants to stop addictive behavior; …providing general information, no providing of personalised advice

21. Mobile apps for providers that help track or manage patient immunizations by assessing the need for immunization, consent form, and immunization lot number; …providing personalized guidance based on personalized specific information (data entered manual, provided by point of care devices or obtained via health records

22. Mobile apps that provide drug-drug interactions and relevant safety information (side effects, drug interactions, active ingredient) as a report based on demographic data (age, gender), clinical information (current diagnosis), and current medications …aggregate population data, provide generic diagnostic or treatment pathways, scientific literature, medical atlases, models and templates as well as

EU ~ Regulated as Medical Device yes / no

software for epidemiologic studies or registers.

23. Mobile apps that enable, during an encounter, a health care provider to access their patient's personal health record (health information) that is either hosted on a web-based or other platform; …does not perform an action on data, or performs an action limited to storage, archival, communication, 'simple search' or lossless compression

24. Mobile apps that allows a user to collect, log, track and trend data such as blood glucose, blood pressure, heart rate, weight or other data from a device to eventually share with a heath care provider, or upload it to an online (cloud) database, personal or electronic health record. …monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual
25. Mobile apps[1] that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions

related to developing or maintaining general fitness, health or wellness, such as those that:

[find examples on the next slide]

- Provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;

[1] When these items are not marketed, promoted or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or do not otherwise meet the definition of medical device, FDA does not regulate them. When they are marketed, promoted or intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or otherwise meet the definition of medical device, FDA intends to exercise enforcement discretion.

- Provide dietary logs, calorie counters or make dietary suggestions;
- Provide meal planners and recipes;
- Track general daily activities or make exercise or posture suggestions;
- Track a normal baby's sleeping and feeding habits;
- Actively monitor and trend exercise activity;
- Help healthy people track the quantity or quality of their normal sleep patterns;
- Provide and track scores from mind-challenging games or generic "brain age" tests;
- Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
- Use social gaming to encourage healthy lifestyle habits;
- Calculate calories burned in a workout.

Bayer Assessment Examples

	General Information / No Personalized Advice	Patient Diary / Communication Chanel	Treatment Reminder	Medical Calculator	Treatment Facilitation	Disease Diagnosis
Whole Body MRI	X					
AF Support / Medical care aids for atrial fibrillation and cerebral infarction	X					
Monthly Me			X			
Pillen Alarm	X	X	X			
myBETAapp		X	X		X	
BETACONNECT™ Navigator			X		X	
Japanese Xarelto App				X		

*typical functions which **are not** medical software relevant*

*typical functions which **are** medical software relevant*

Non Medical Device Apps

App Desription

Whole Body MRI
The Gadovist Whole Body MRI App from Bayer Healthcare is aimed at medical professionals in the field of radiology. The App Includes a collection of 15 cases and illustrates the diagnostic competence of dynamic contrast-enhanced MRI utilizing Gadovist 1.0 in diverse parts of the body like joints, brain, heart and others.

App look like

App Function & Regulation

Providing information for training of physicians.

Medical Device Directive 93/42/EEC
Apps which might not be a medical device providing general information, no providing of personalized advice.

Appendix B of FDA Mobile Medical Application Guideline describes that FDA intends to exercise enforcement discretion for mobile apps that provide educational information or reminders or GPS location

General Function

General Information / No Personalized Advice

Non Medical Device Apps

App Desription

AF Support / Medical care aids for atrial fibrillation and cerebral infarction
This application helps physicians to explain pathogenesis of atrial fibrillation, pathogenesis of cardiogenic cerebral embolism, role of anticoagulation therapy and its risk of bleeding to patients.
These are available for primary prevention, secondary prevention, and patients with either.

App look like

App Function & Regulation

Providing information for Health Care Professionals to enable better patient education.

Medical Device Directive 93/42/EEC
Apps which might not be a medical device providing general information, no providing of personalized advice.

Appendix B of FDA Mobile Medical Application Guideline
describes that FDA intends to exercise enforcement discretion for mobile apps that provide easy access to information related to health conditions or treatments ... that provide educational information or reminders or GPS location

General Function

General Information / No Personalized Advice

Non Medical Device Apps

App Desription

Monthly Me
This App is intended to help collect and organize information about menstrual pain and bleeding, and their impact on women's daily life. If women are concerned about the intensity, pattern or frequency of pain and bleeding, then collecting this information through this app may be useful to guide conversations with a physician. Allows women to enter data, quickly review data in a calendar, and included reporting features.

App look like

App Function & Regulation

Tracking of menstrual cycle information with out effect on the decision of the health care professional and the patient treatment.

Medical Device Directive 93/42/EEC
Apps which might be a medical device …monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual

Appendix B of FDA Mobile Medical Application Guideline
describes that FDA intends to exercise enforcement discretion for mobile apps that help patients/users self-manage their disease or condition without providing specific treatment suggestions. …help patients document, show or communicate potential medical conditions to health care providers

General Function

Patient Diary/Communication Chanel

Non Medical Device Apps

App Desription

Pillen Alarm
Forgot a pill? Safe contraception wanted? The pill alarm against oblivion of the pill has many features around the topic of contraception and information on topics as menstruation cycle, pill and gynecologist.
Is it possible to daily remember taking the pill, carry a cycle calendar, schedule the next visit at the gynecologist and time for the next recipe.

App look like

App Function & Regulation

Providing treatment reminder, calendar management function and information for patient education.

Medical Device Directive 93/42/EEC
Apps which might not be a medical device communication with healthcare providers (booking appointments, request prescriptions, virtual consultation…)

MHRA guidance "Borderline with medical devices"
Pill reminder devices are not considered as medical devices

Appendix B of FDA Mobile Medical Application Guideline describes that FDA intends to exercise enforcement discretion for mobile apps that provide educational information or reminders or GPS location

General Function

General Information/No Personalized Advice, Treatment Reminder, Patient Diary/Communication Chanel

Medical Devices

App Desription

myBETAapp
myBETAapp™ is a personal reminder and tracker for your BETASERON® (interferon beta-1b) injections, offered as part of the BETAPLUS™ program. This app makes it easy to remember when and where to inject BETASERON and to keep a diary that you can choose to share with your healthcare team.

App look like

App Function & Regulation

Medical device Class I
Providing calendar management function and a treatment reminder. The app also suggests an injection site (from the list in the BETASERON product insert, which can be further narrowed by the patient), based on the last site recorded by the user in the software and in accordance with a rotation schedule.

Medical Device Directive 93/42/EEC
Apps which might be a medical device **…monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual**
… if the software does not **perform an action on data**, or performs an action limited to storage, archival, communication, ‘simple search’ or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device.

FDA
The myBETAapp is seen as a device consitiounent part of the combination product BETOACONNECT system

General Function

Communication Chanel/Patient Diary, Treatment Reminder, Treatment Facilitation

BETACONNECT™ Navigator

App Desription

BETACONNECT™ Navigator
The BETACONNECT™ Navigator is a web-based application that can help you provide greater support and enjoy increased patient communication, both major factors in enhancing patient adherence to therapy.

The BETACONNECT™ Navigator is your interface with the BETACONNECT™ system, just as myBETAapp™ is for patients. It provides a comprehensive level of patient information in a single screen

App look like

App Function & Regulation

Medical device Class I
The BETACONNECT™ Navigator gives a consolidated view of your patients' adherence to therapy, based on information they record through myBETAapp™. Within the BETACONNECT™ Navigator, you can generate reports about patient activity over time in just a few, quick steps. Simply select a time period and the patients you wish to include, and hit a button to create your report.

Medical Device Directive 93/42/EEC
Apps which might be a medical device **…monitoring of patient, collecting manual entered or automatically measured information, if outcome affects the treatment of an individual**
… if the software does **not perform an action on data**, or performs an action limited to storage, archival, communication, 'simple search' or lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) it is not a medical device.

FDA
The myBETAapp is seen as a device consitiounent part of the combination product BETOACONNECT system

General Function

Treatment Reminder, Treatment Facilitation

Xarelto App Japan / 診療計算 App

App Desription

Xarelto App Japan / 診療計算 **App**
Japanese Xarelto App is an medical calculation app with a creatinine clearance, risk of bleeding and stroke risk consideration. Intended for the Health Care Professionals for treatment facilitation and dosage calculation .

App look like

App Function & Regulation

Medical device Class I
This tool makes a dosas recommendation of the specific patient under specific circumstances. . The treatment process of the physician is affected. This app does contain the creatine clearance calculator.

Medical Device Directive 93/42/EEC
Software that has a medical purpose ...diagnosis, prevention, monitoring, treatment or alleviation of disease

General Function

Medical Calculator

Medical Software Expert Committee

Chairman

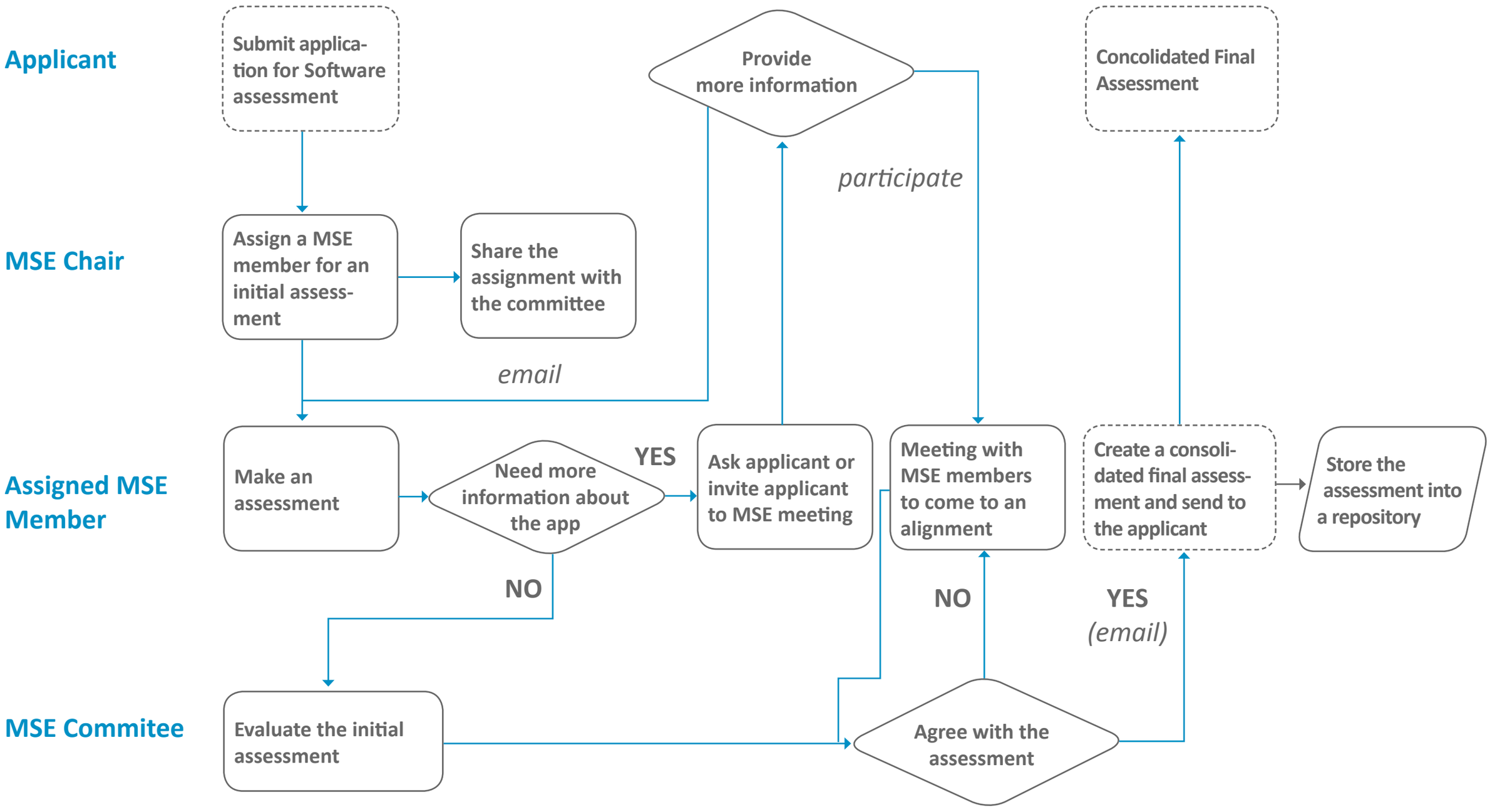
- Hal Zabin, *Regulatory Affairs*

Committee Member

- Peter Podhaisky, *Regulatory Affairs*
- Achim Hermann, *Regulatory Affairs*
- Hal Zabin, *Regulatory Affairs*
- Garo Mimaryan, *Regulatory Affairs*
- Karym El Sayed, *Medical Device Software Development*
- Melanie Aust, *Anti-Counterfeiting & Device Changes*
- Michael Ruetz, *Development Quality Assurance*
- Juraj Voloch, *Biotech Global Quality*
- Sigrid Achenbach, *Development Legal*
- Patrick Grigas, *Integrated Multi Chanel Marketing*

MSE-Committee process

Process to decide on “borderline” software application whether software under development (or changes to marketed software lead to medical software) is to be classified as medical software and has to be developed according to the requirements of the AS development process


Applicant
MSE Chair
Assigned MSE Member
MSE Commitee
Submit application for Software assessment
Assign a MSE member for an initial assessment
Share the assignment with the committee
Provide more information
participate
email
Concolidated Final Assessment
Make an assessment
Need more information about the app
YES
Ask applicant or invite applicant to MSE meeting
Meeting with MSE members to come to an alignment
Create a consolidated final assessment and send to the applicant
Store the assessment into a repository
NO
NO
YES
(email)
Evaluate the initial assessment
Agree with the assessment