EU Law and Life Sciences – Mobile Health Apps

Webinar - Brussels, 9 July 2014

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Agenda

- Covington at a glance
- Mobile health apps - opportunities
- Mobile health apps – Regulatory classification
- Consequences of classification as medical device
- Further legal aspects to consider
- Competition law and mHealth apps

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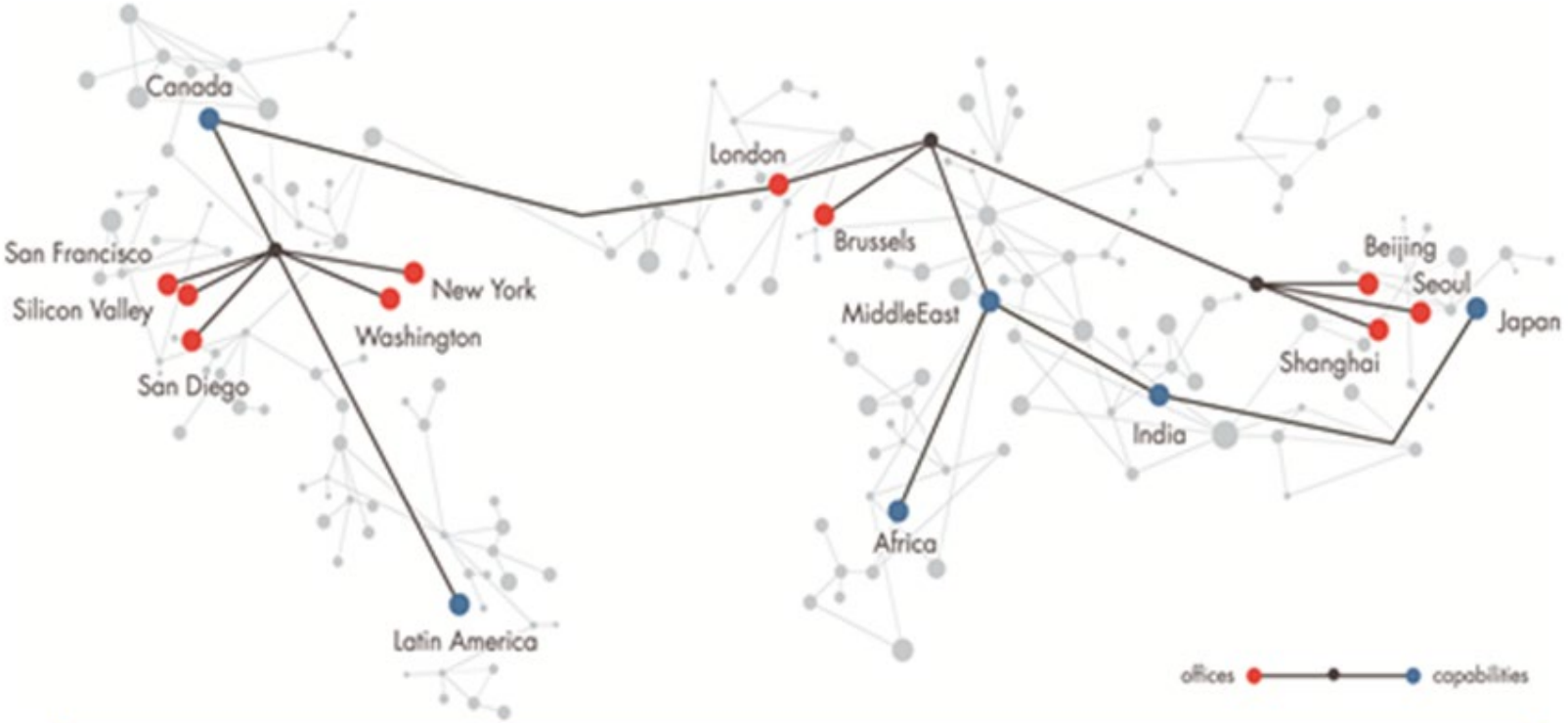

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Covington's life sciences practice

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Life Sciences Tier 1

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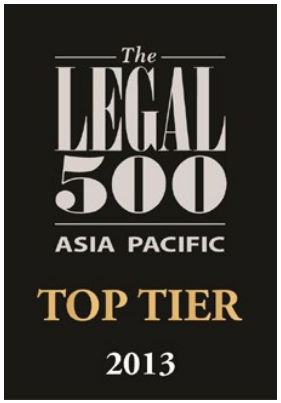
Pharmaceuticals & Biotechnology TopTier



Health Care: Life Sciences TopTier

Mobile health apps - Opportunities

- Pharmaceutical and Medical Devices Companies
- Wellness, LifeStyle, Health, Sports sector
- Technology sector companies
- Software companies
- Physicians, other HCP and medical institutions
- Specific Service Providers and Consultants
- Notified Bodies
- Payers (Healthcare insurance funds, NHS etc.)
- Patients and carers

Mobile Health Apps

Some Examples

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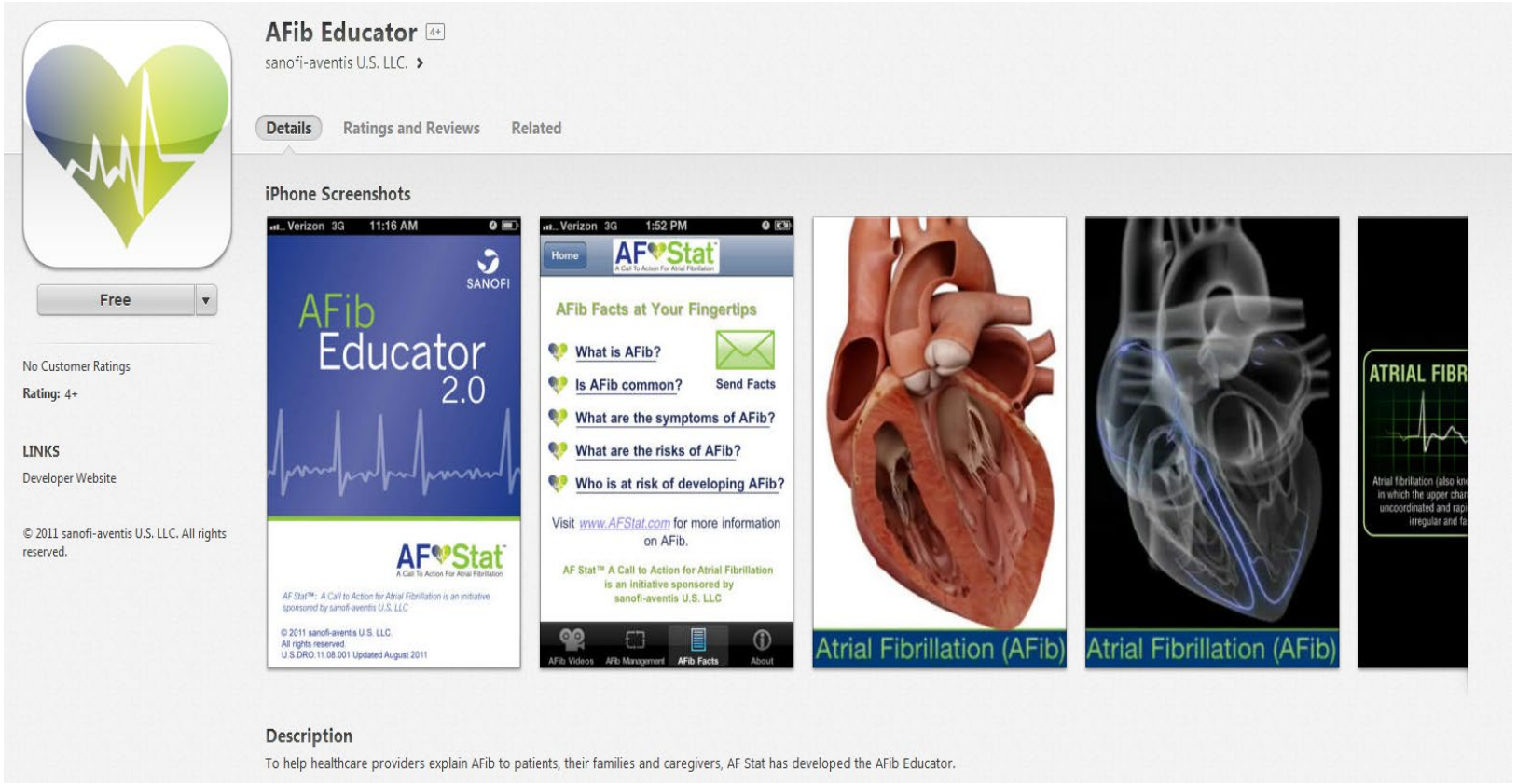
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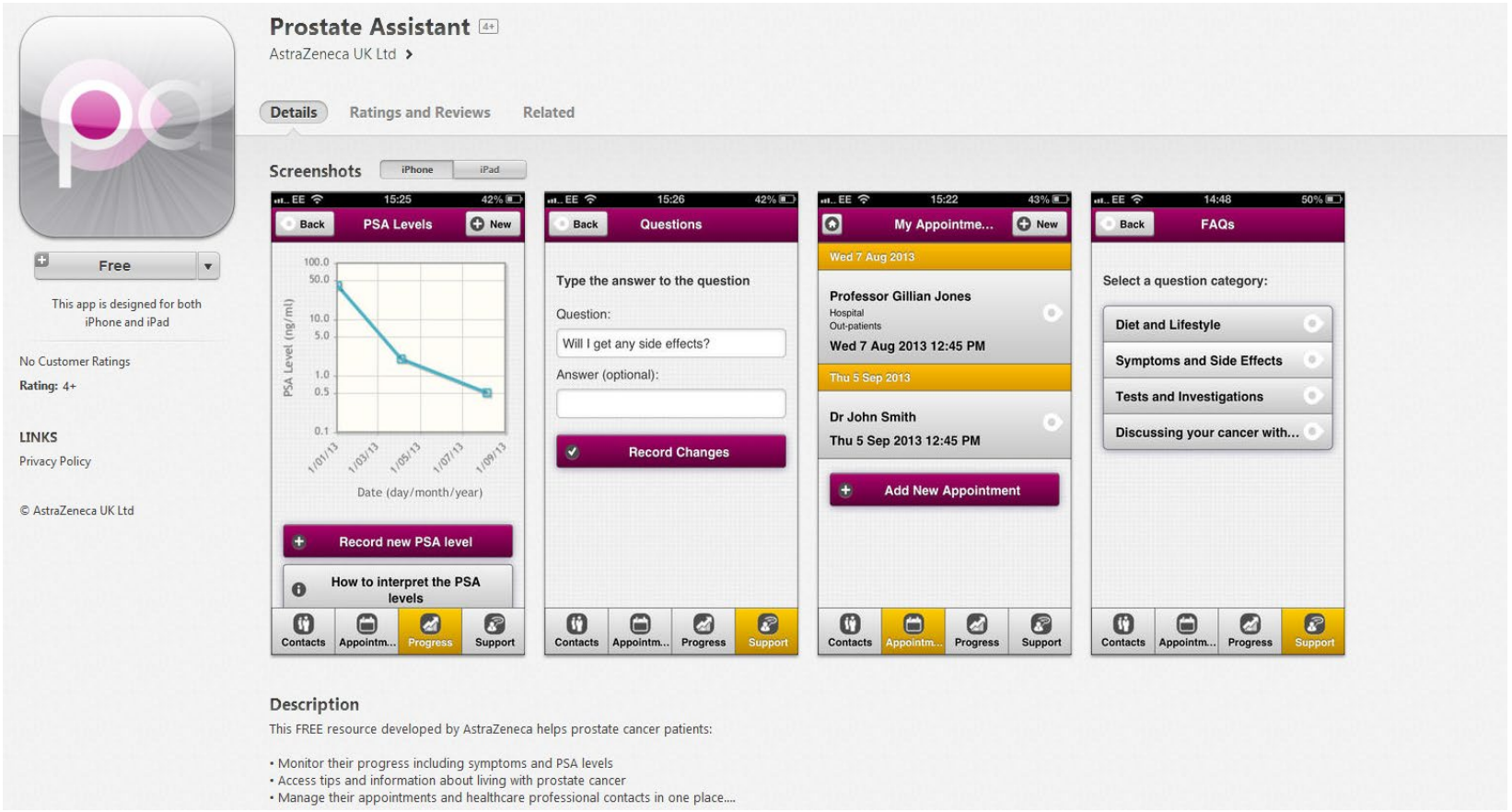
About
Atrial Fibrillation (AFib)
Atrial Fibrillation (AFib)
ATRIAL FIBR
Description
To help healthcare providers explain AFib to patients, their families and caregivers, AF Stat has developed the AFib Educator.

Prostate assistant



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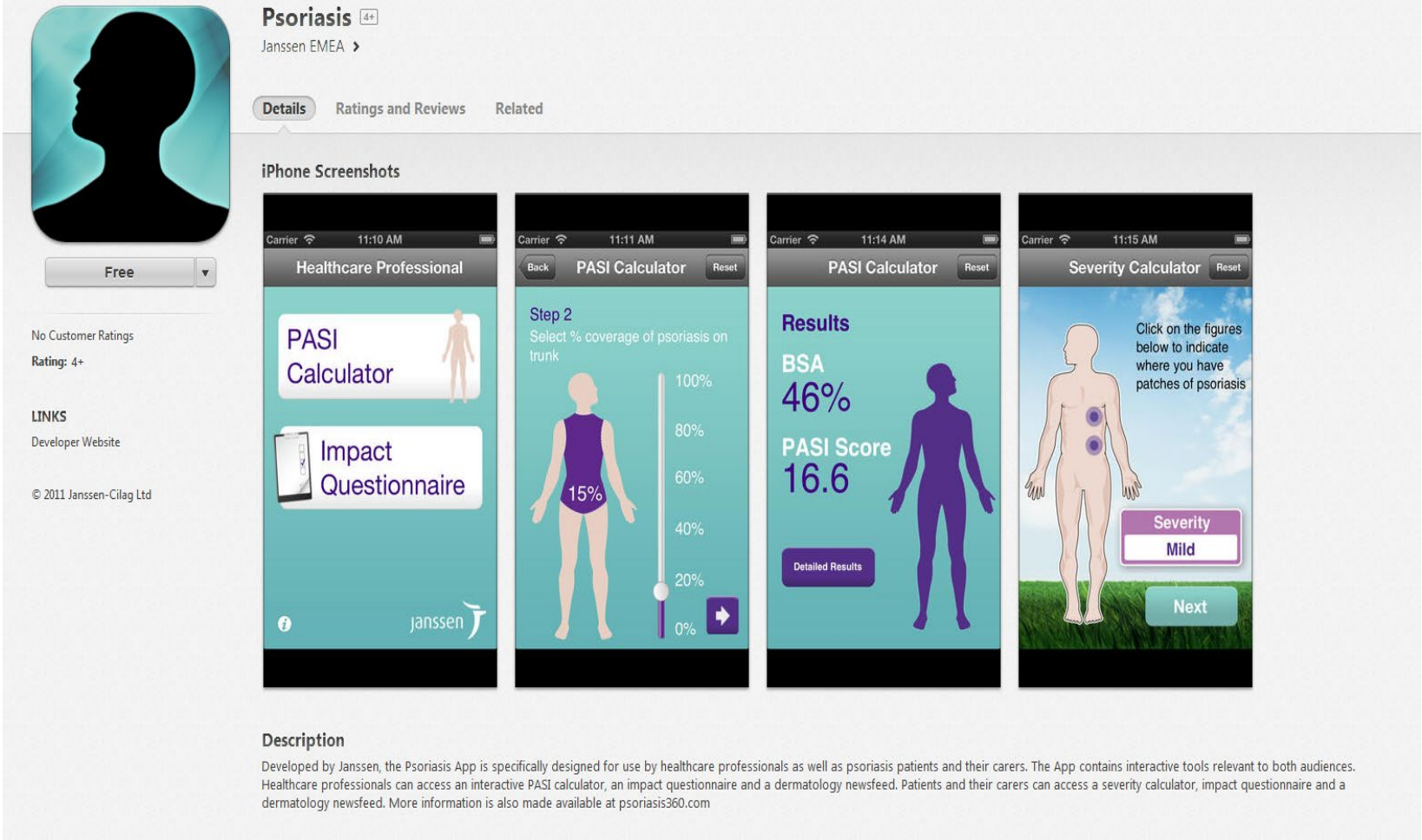
Psoriasis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Step 2
Select % coverage of psoriasis on trunk
15%
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80%
60%
40%
20%
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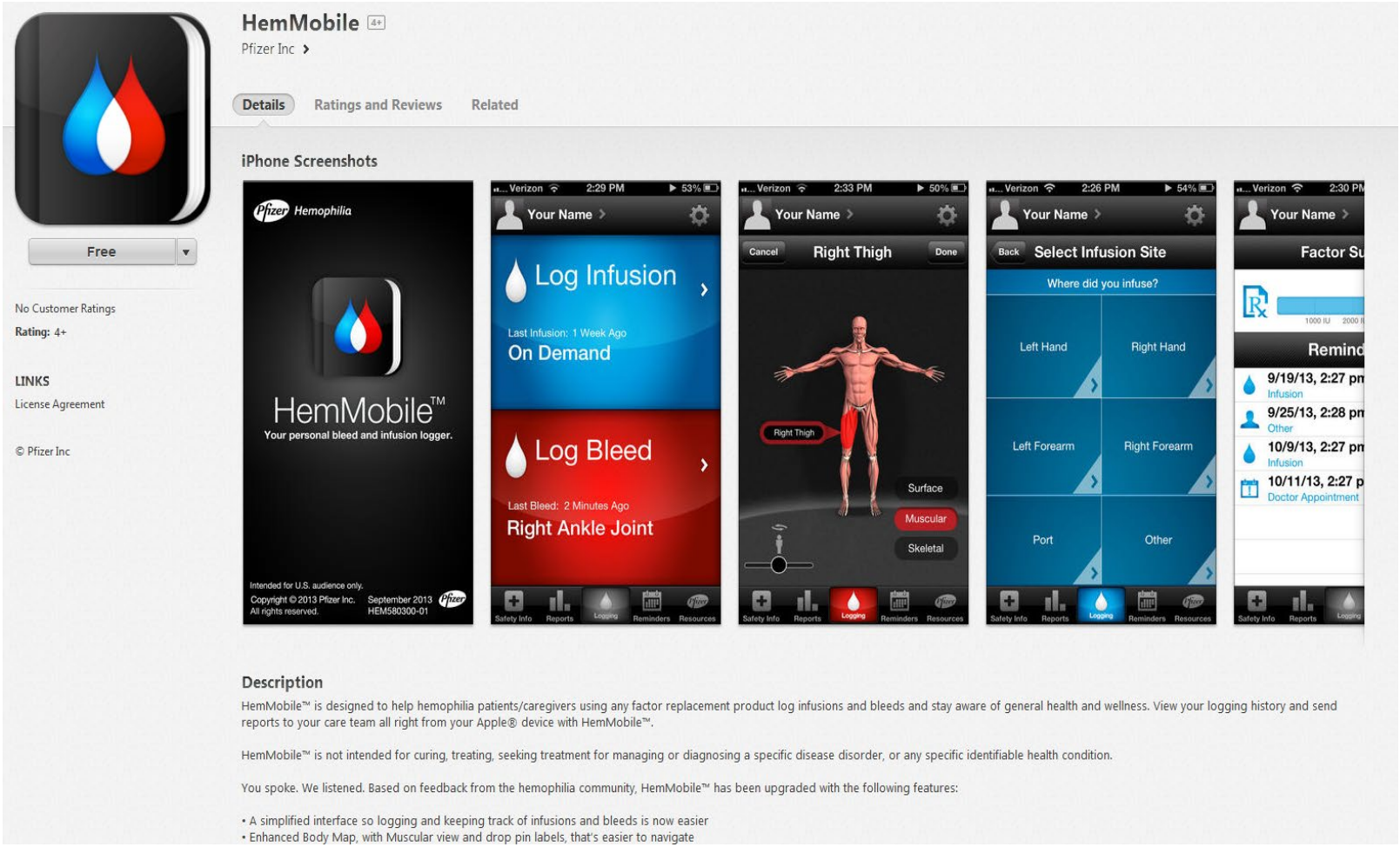
Carrier 11:14 AM
PASI Calculator
Reset
Results
BSA
46%
PASI Score
16.6
Detailed Results
Carrier 11:15 AM
Severity Calculator
Reset
Click on the figures below to indicate where you have patches of psoriasis
Severity
Mild
Next
Description
Developed by Janssen, the Psoriasis App is specifically designed for use by healthcare professionals as well as psoriasis patients and their carers. The App contains interactive tools relevant to both audiences. Healthcare professionals can access an interactive PASI calculator, an impact questionnaire and a dermatology newsfeed. Patients and their carers can access a severity calculator, impact questionnaire and a dermatology newsfeed. More information is also made available at psoriasis360.com

Hemmobile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Last Infusion: 1 Week Ago
On Demand
Log Bleed
Last Bleed: 2 Minutes Ago
Right Ankle Joint
Safety Info
Reports
Logging
Reminders
Resources
Cancel
Right Thigh
Done
Right Thigh
Surface
Muscular
Skeletal
Back
Select Infusion Site
Where did you infuse?
Left Hand
Right Hand
Left Forearm
Right Forearm
Port
Other
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9/19/13, 2:27 pm
Infusion
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Other
10/9/13, 2:27 pm
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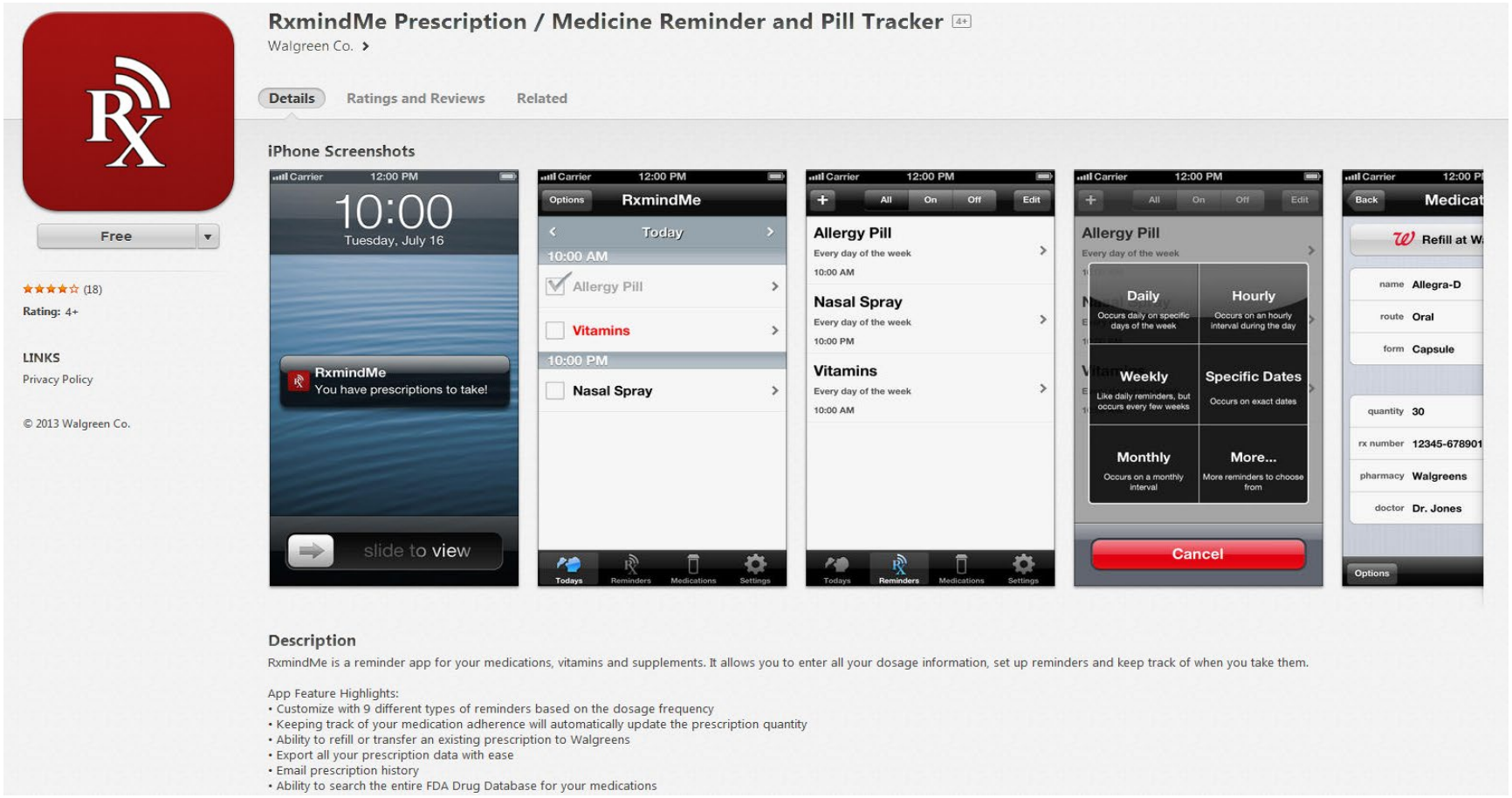
Doctor Appointment
Description
HemMobile™ is designed to help hemophilia patients/caregivers using any factor replacement product log infusions and bleeds and stay aware of general health and wellness. View your logging history and send reports to your care team all right from your Apple® device with HemMobile™.
HemMobile™ is not intended for curing, treating, seeking treatment for managing or diagnosing a specific disease disorder, or any specific identifiable health condition.
You spoke. We listened. Based on feedback from the hemophilia community, HemMobile™ has been upgraded with the following features:
• A simplified interface so logging and keeping track of infusions and bleeds is now easier
• Enhanced Body Map, with Muscular view and drop pin labels, that's easier to navigate

Rxmindme prescription



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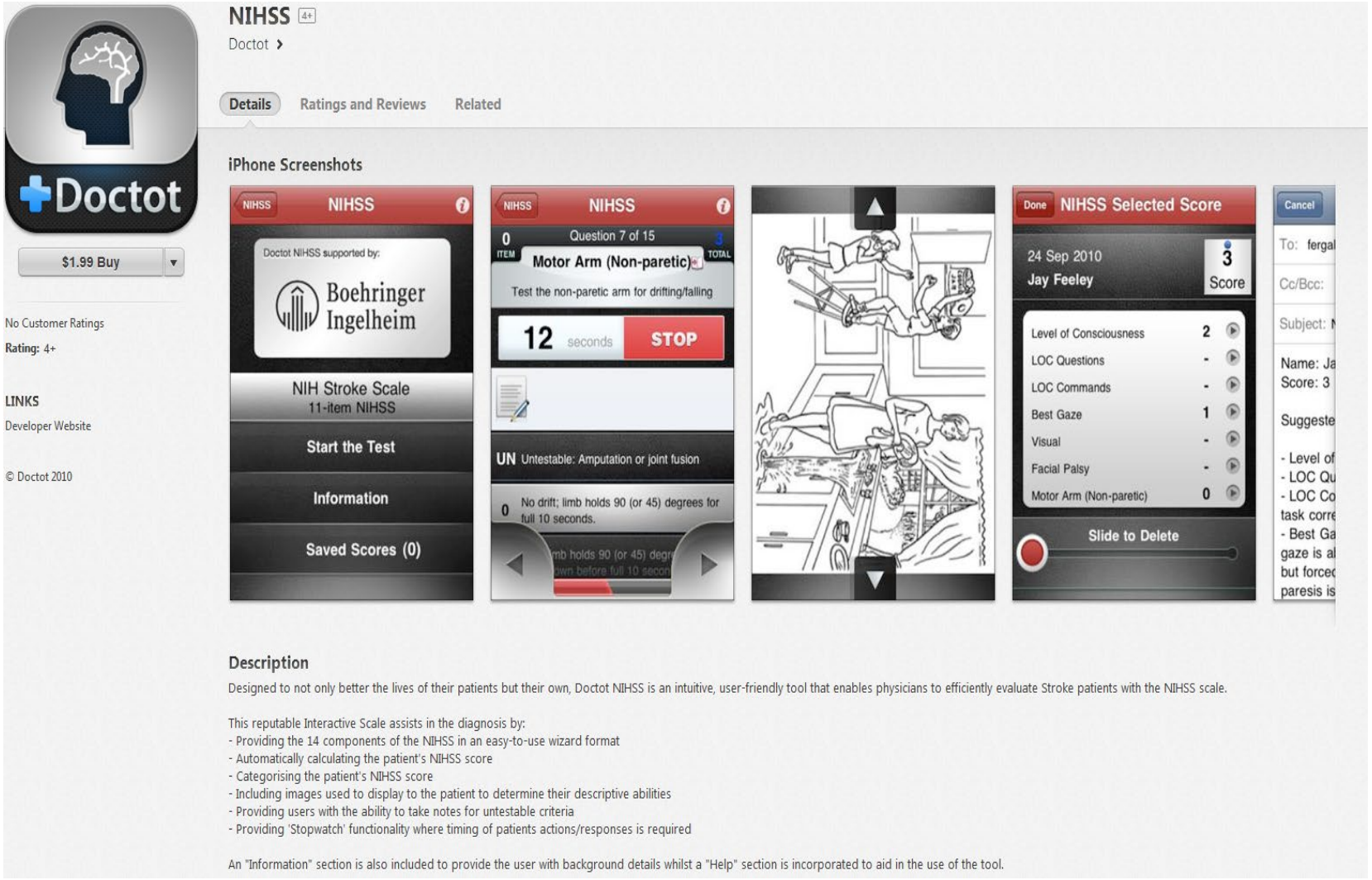

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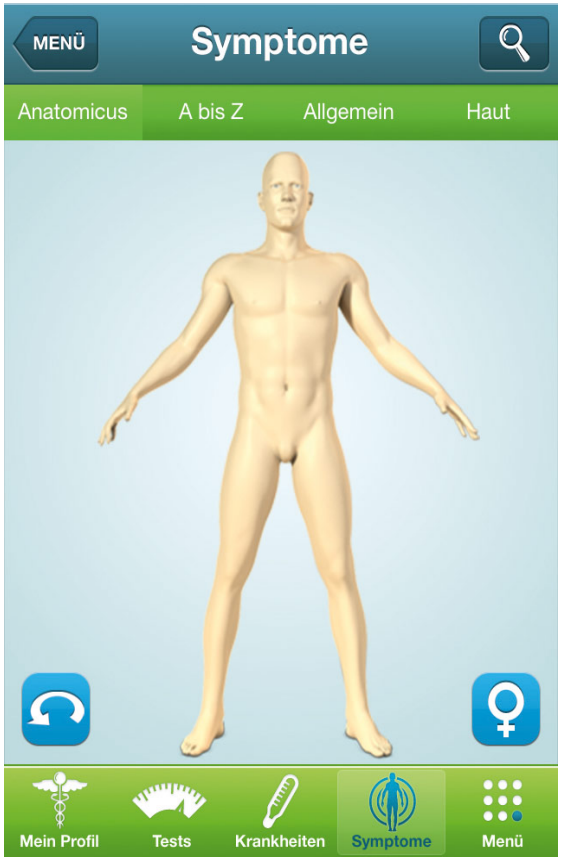
Further examples for mobile health apps



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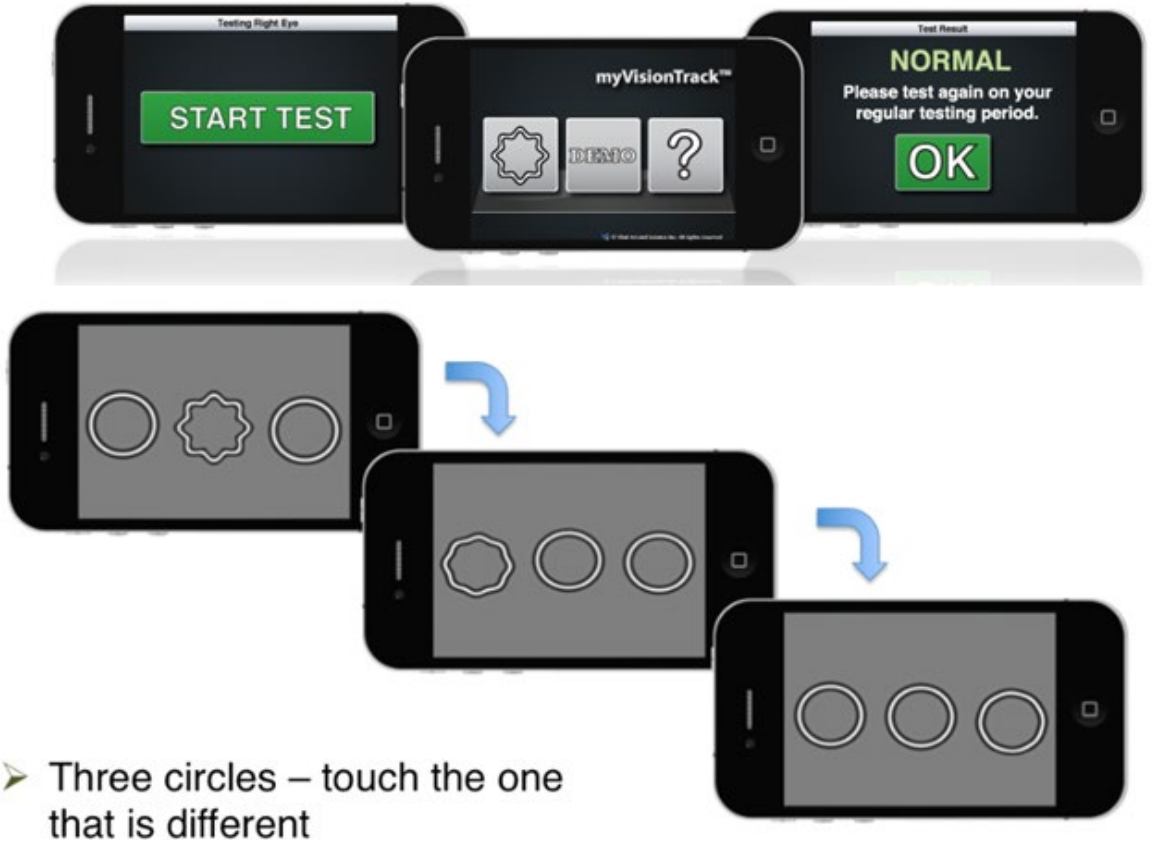
myVisionTrack



myVisionTrack™ is an accurate, portable, and user-friendly system that enable patients with retinal diseases to quickly and efficiently monitor their own vision function at home.

Source: http://myvisiontrack.com/myvisiontrack/myvisiontrack-overview/

Regulatory and legal aspects

- **Key question:**

  Regulatory Classification of the mHealth Apps?

  - **is the app a medical device or not?**
  - **which consequences apply if yes, or if no?**

- **Other regulatory and legal aspects**

Medical devices laws in the EU

- Art. 1 (2)a EU Medical Devices Directive 93/42/EEC
  - Legal Definition of a medical device
  - National Implementation in EU Member States

  - MEDDEV 2.1/6
    - Guideline of European Commission on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices
    - For interpretation purposes only (non binding) and primarily prepared for stand alone software
    - The decision tree provided in the guidance document is not sufficient from a legal perspective and even misleading

Definition of medical devices

"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 the purpose of:

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

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Definition of medical devices

- Key aspects of the medical devices definition are
  - (1) Pertinent product category
  - (2) Intended purpose of the product
  - (3) Action of the product in or on the human body
  - (4) Mode of action

Definition of medical devices

- Intended purpose and action of the product
  - Scope of the **intended purpose** must be covered by alternatives a)-d) of the medical devices definition
    a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
    b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
    c) investigation, replacement or modification of the anatomy or of a physiological process,
    d) control of conception,
  - **Principal intended action** in or on the human body
  - Determination of the intended purpose
    - Depends on information and data provided by manufacturer (e.g., with with labelling, instructions, advertisement)
    - Perspective for Assessment („*Auslegungshorizont*“)?

Regulatory classification of apps

- Required action in or on the human body
  - Central element for assessment of apps
  - Medical device must unfold „an action in or on the human body“
  - But:
    - Mobile Health Apps as Software products generally do not have a physical contact with the human body
  - Legal analysis:
    - For apps, a software-specific interpretation of this definition element is required.

Regulatory classification of apps – The (partly misleading) MEDDEV guidelines

EUROPEAN COMMISSION
DG HEALTH AND CONSUMER
Directorate B, Unit B2 "Health Technology and Cosmetics"

MEDICAL DEVICES: Guidance document

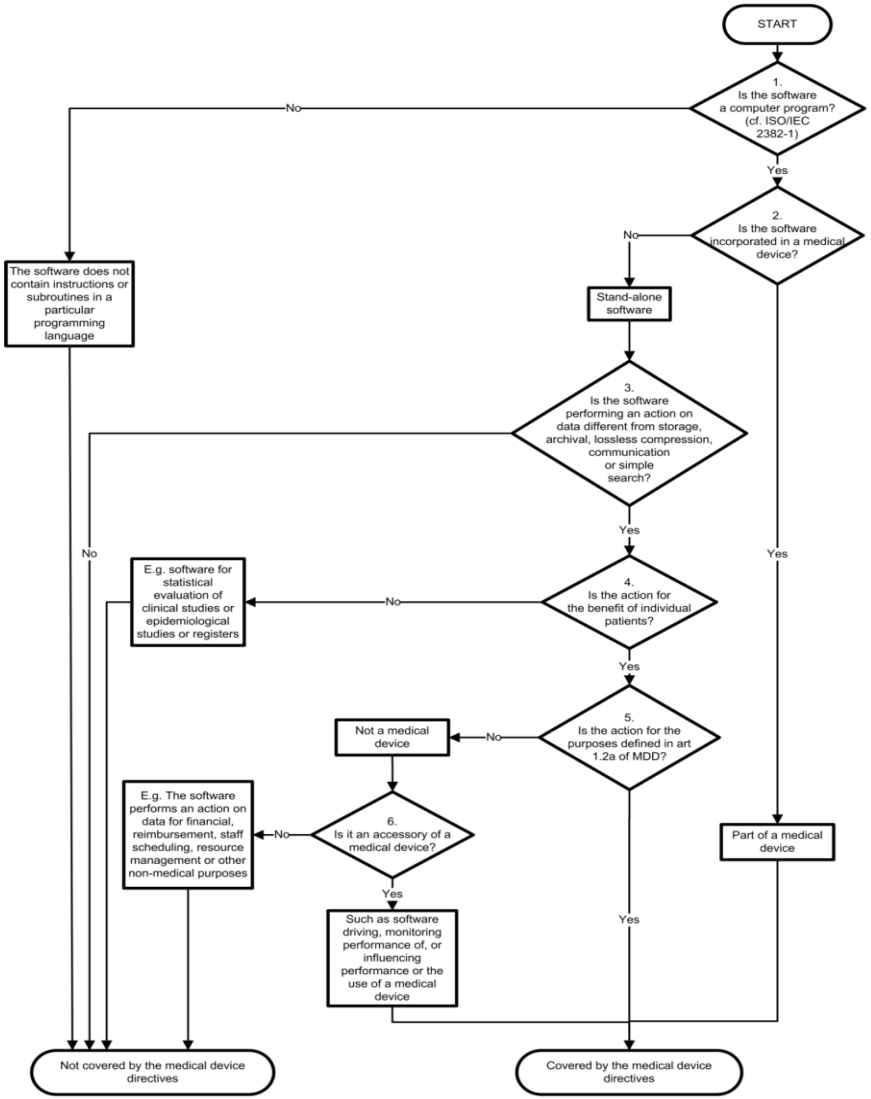
-

Qualification and Classification of stand alone software

MEDDEV 2.1/6
January 2012

GUIDELINES ON THE QUALIFICATION AND CLASSIFICATION OF STAND ALONE SOFTWARE USED IN HEALTHCARE WITHIN THE REGULATORY FRAMEWORK OF MEDICAL DEVICES

Regulatory classification of apps - The (partly misleading) MEDDEV guidelines



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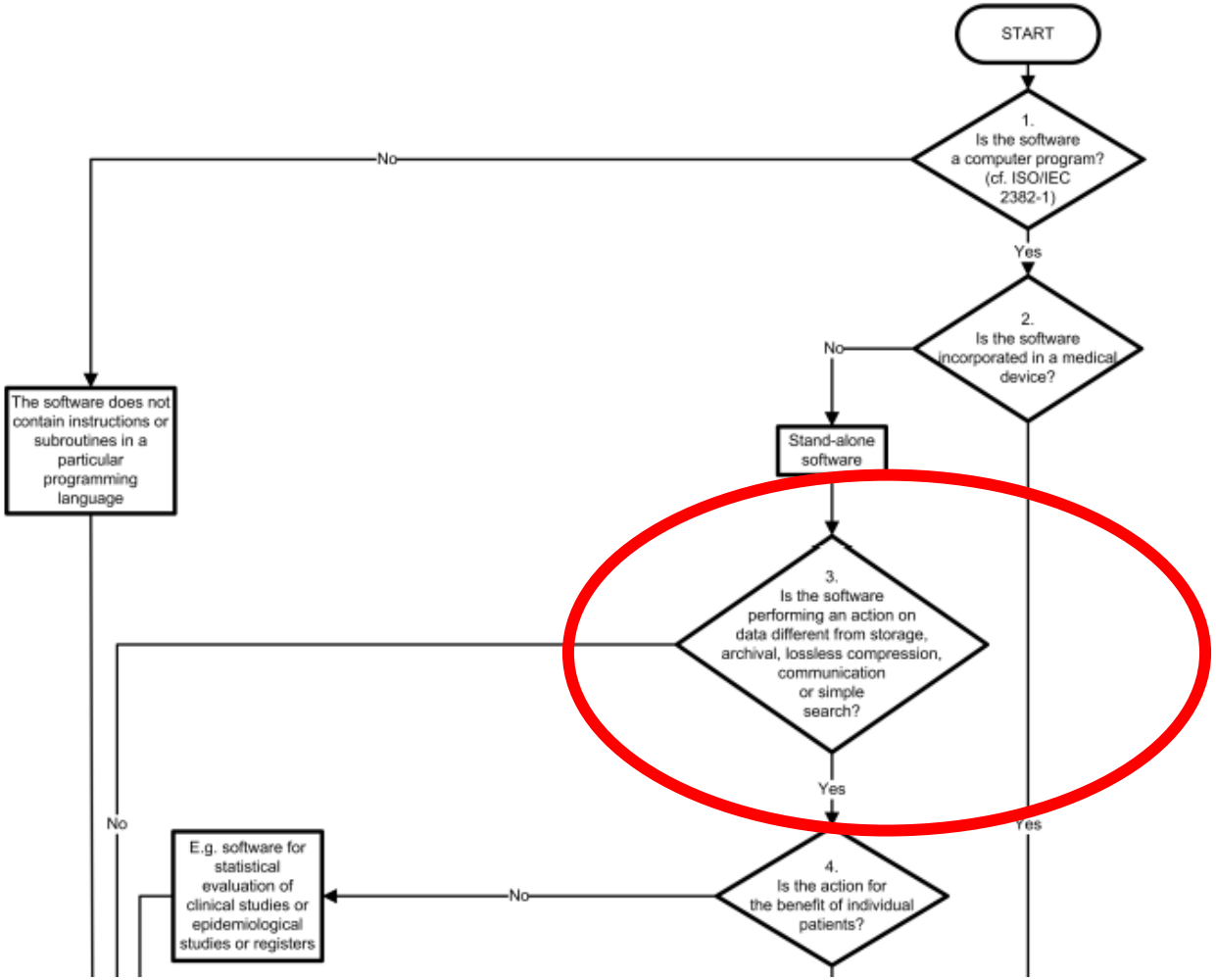
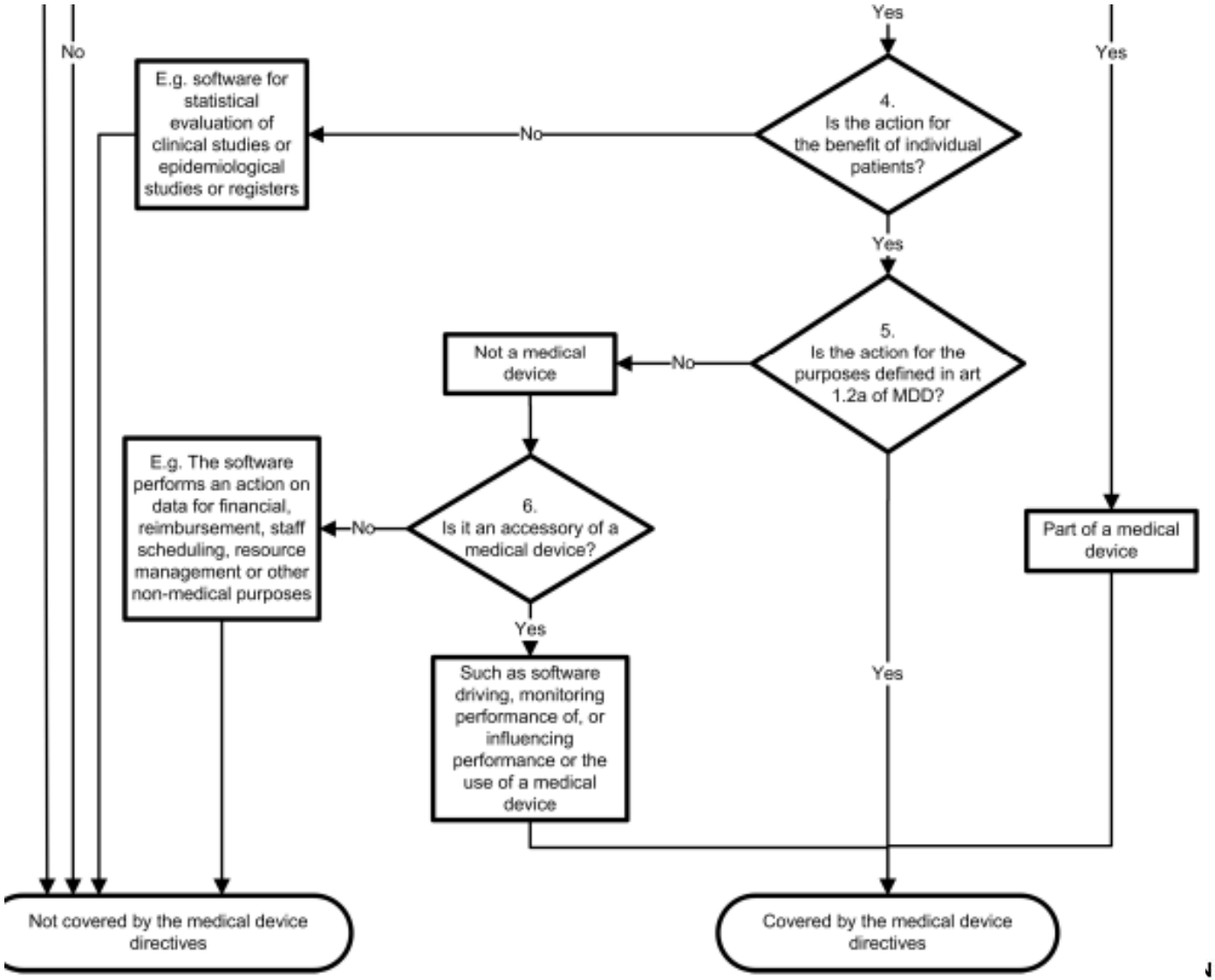
Regulatory classification of apps - The (partly misleading) MEDDEV guidelines



Regulatory classification of apps - The (partly misleading) MEDDEV guidelines



Regulatory classification of apps - The (partly misleading) MEDDEV guidelines

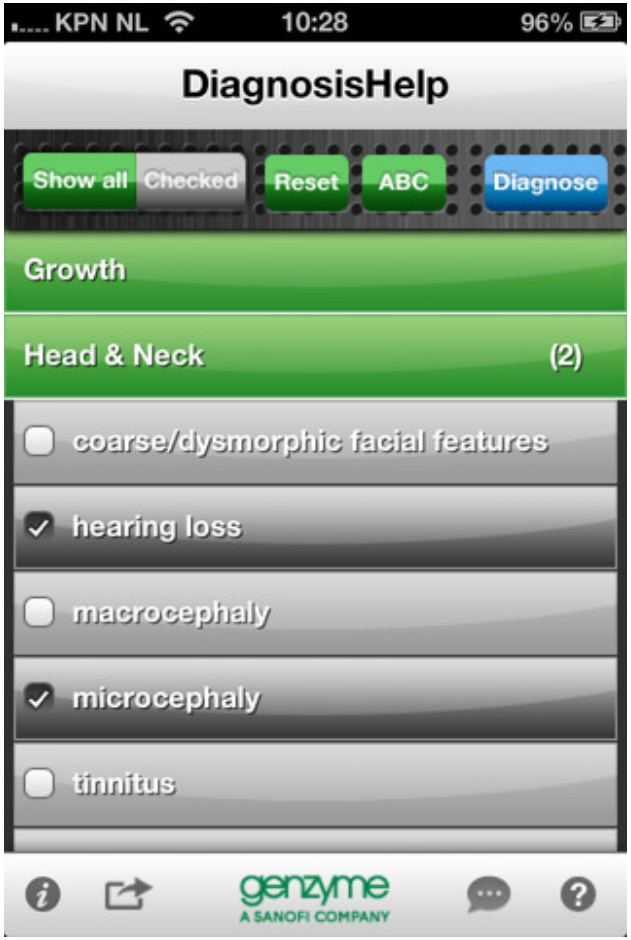
- **Key Insufficiencies of MEDDEV 2.1/6 re. Apps**
  - MEDDEV 2.1/6 excludes all software products from the medical devices definitions that
    - do not perform an action on data or perform an action limited to storage, archival, communications or which only offer simple search or lossless compression of data.
  - This is questionable from a legal perspective: For example, what about an App that only stores patient data but is offered for the intended purpose (e.g.) to be used for “diagnosis/monitoring of xyz disease…”?
  - In fact, such App qualifies as a “medical device” under EU laws – the MEDDEV 2.1/6 decision tree is misleading here!
  - The presentation of the app is of utmost importance.
  - Other - and more software-specific - criteria need to be applied than those in MEDDEV 2.1/6

Examples for the classification of apps

- Action for the benefit of an individual person (not necessarily a patient)?
  - Non-patients are also included here (e.g., apps for disease prevention purposes)
  - App intended to be used for evaluation of patient data to trigger medication **(+)**
  - Particular issues

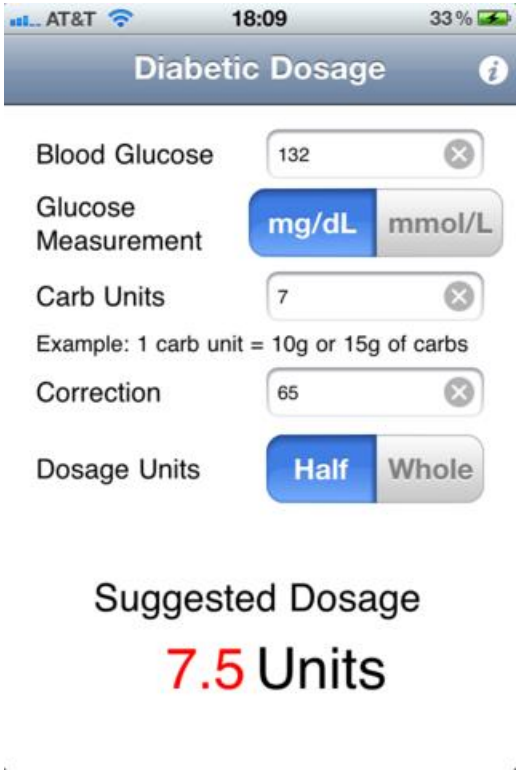
Examples for the classification of apps

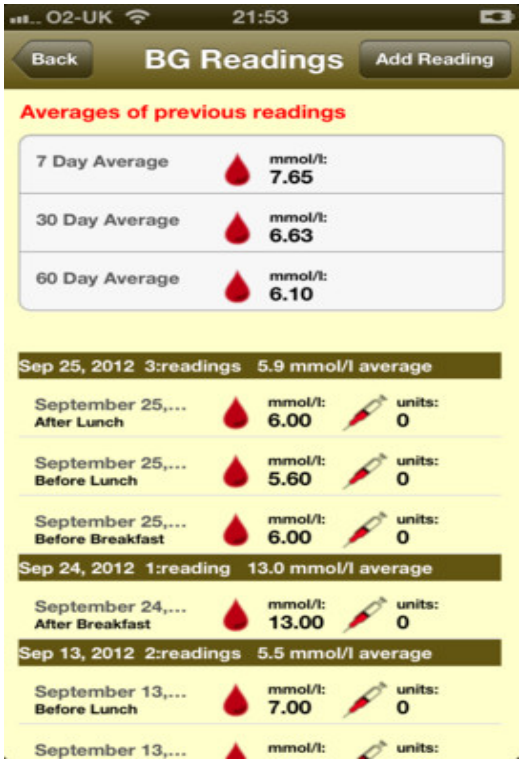
- Intended purpose covered by the Medical Device Definition?
  - Distinction between medical and wellness purposes
    - e.g. improvement of quality of live, promotion of health or healthy nutrition
  - presentation of app is important for determining intended purpose
    - category in app store, health care professionals as targeted users, key words, special functions etc.



Examples for the classification of apps

- Diagnosis tool ./. simple search?
- Diabetes tool ./. mere storage ./. action on patient data?





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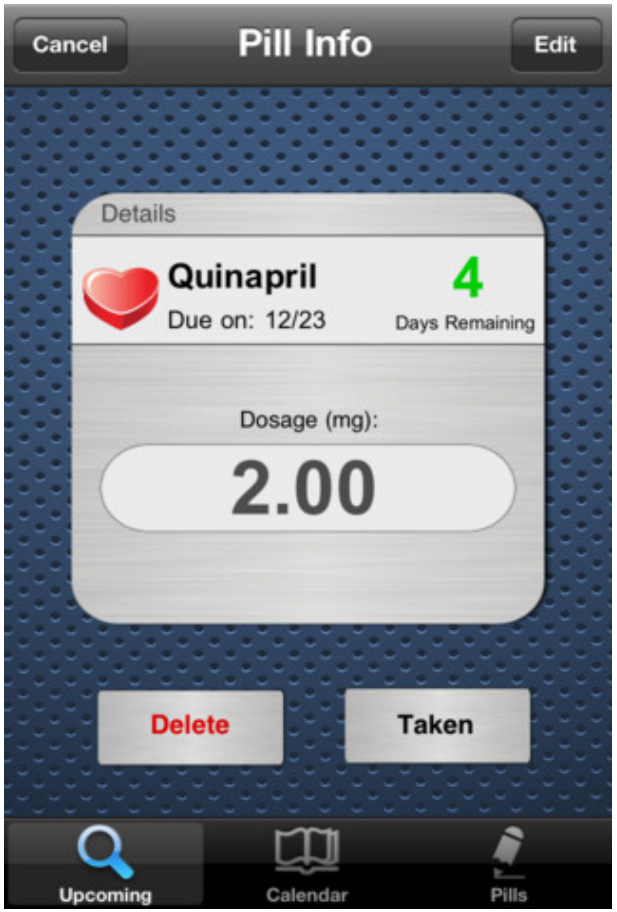
Examples for the classification of apps

- Principal intended purpose
  - EU Guideline defines
    - software that does not perform an action on data, or performs an action limited to storage, archival, communication, ‚simple search' or lossless compression is not a medical device
    - Borderline case „Pill Reminder"
      - only time calculator or storage (-) or calculation of intake interval/dosage (+)



Further classification and regulatory challenges

- Accessory to a medical device?
  - App itself may not be classified as a medical device but can fall under the Medical Devices Regulation as
    - a means necessary for the proper function of a medical device (e.g., “steering software”) or
    - an “accessory” to a medical device

      Definition: 'accessory' means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device;

Further classification and regulatory challenges

- Consequences of qualifying as medical device
  - Classification of the medical device in risk classes
  - CE-marking under EU laws required
  - Clinical evaluation/validation required (including information on development lifecycle, risk management, etc.)
  - Developers, manufacturers, legal manufacturer and suppliers subject to regulatory supervision
  - Medical Devices Vigilance requirements (including appointing “safety officer” in some EU countries)
  - Rules on advertisement for medical devices apply
  - Also unfair competition risks in case of non-compliance

- Other Regulatory Considerations and Challenges

Further legal aspects to consider

- Establish clear legal relationships (app developer, OEM, “legal manufacturer”, app store, user, consultants)
- Contracts, Terms of Use, Licences
- IP-rights
- Liability Risks and Contractual Risk Management
- Data Protection and Data Security requirements
- Which laws apply?
- Lack of Standards and Harmonization - ongoing efforts of regulators for “global harmonization”
- Market Access & Reimbursement

- **Competition law considerations**

Competition law and mHealth Apps

Introduction

- EU Competition law applies to all sectors and practices, including mhealth
- EU Competition rules typically apply to:
  - Cooperation between competitors
  - Unilateral conduct
- A variety of competition law problems may arise depending on the market actors, the level of value chain in which the conduct takes place, the competitiveness of the market, etc.

Cooperation between market actors

- Development of mhealth services will typically be based on collaboration between different market actors including competitors (e.g., pharmaceutical companies) and non-competitors (e.g., pharmaceutical companies and technology services providers)

- Collaboration between companies typically triggers the application of Article 101(1) TFEU which prohibits agreements which may have an adverse impact on competition. However, many mhealth related collaborations will be justified under Article 101(3) TFEU, to the extent they are a source of efficiencies that benefit consumers

Example of cooperation between market actors

- Data pools
  - Creation of health data pools associating data from pharmaceutical companies, patients, healthcare providers, insurances, etc.
  - Sharing data between competitors is usually looked at suspiciously by competition authorities
  - However, in this case, sharing of health-related data could be highly beneficial (assuming it complies with other regulatory obligations)

Unilateral conduct

- Technology markets are often prone to the creation of significant market power because of network and scale effects

- When such market power is present, competition authorities will carefully monitor the behaviour of dominant firms to ensure they do not engage in exclusionary conduct such as customer lock-in or foreclosure of competitors by making switching to other devices, software, services or products more difficult

Mobile Health Apps

Many thanks!

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Presenter Profile: Adem Koyuncu

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Adem Koyuncu is double qualified as lawyer and medical doctor and is a partner in Covington's Brussels office. He is heading the German Life Sciences-practice and is also member of the Compliance group of the firm.

Adem focuses his practice on advising Life Sciences industry clients. His clients include pharmaceutical and medical devices companies as well as service providers and technology companies active in the life sciences sector.

Prior to joining Covington, Adem was a partner of the international law firm Mayer Brown LLP in Düsseldorf, Germany, and co-head of that firm's global life sciences group. Before joining legal practice, he worked in the pharmaceutical industry and also practised as a medical doctor.

Adem is a German-qualified lawyer and licensed to practice law in Germany. He is also member of the bar in Brussels, Belgium.

Adem has advised several clients on the classification and legal requirements for mobile health apps as well as other medical software, eHealth tools and complex telemedicine systems.

Adem is "*highly recommended as a leading lawyer in Life Sciences*" (Chambers Europe 2013) and also recognized by other legal directories.

Presenter Profile: Damien Geradin

Damien Geradin

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Professor **Damien Geradin** is a competition law and regulatory partner in the Brussels office of Covington & Brussels, a Washington, DC-based international law firm comprising 850 lawyers spread in eight locations. His practice focuses on complex competition and regulatory cases in the high-technology and life sciences fields.

Damien is a Professor of law at Tilburg University and George Mason University School of Law. In the past, he held visiting professorships at Columbia, Harvard, Michigan and Yale universities. He is the editor of the Journal of Competition Law & Economics. Damien has authored/edited over 20 books and 80 law review articles.

Damien is listed as a competition, regulatory law expert in Legal 500, Who's Who Legal, GCR, Chambers and other legal guides. Damien is a non-governmental adviser (selected by the European Commission) and contributor to the ICN's committee on single-firm conduct.

Damien graduated obtained a law degree (magna cum laude) from the University of Liège in 1989, a LLM from King's College London in 1990 and a PhD in law from Cambridge University in 1995. In 1997-98, Damien was a Fulbright scholar and a visiting lecturer at Yale Law School.