Consumer Mobile Health Application Functional Framework (cMHAFF) Overview and Update

Mobile Health

May 2018

HL7 Cologne, Germany WGM

cMHAFF Scope and Goals

- Provide a framework for assessment of the **common foundations** of mobile health apps
  - Product Information (disclosures/transparency)
  - Security
  - Privacy/consent/ authorization
  - Risk assessment/analysis
  - Data access privileges
  - Data exchange/sharing
  - Usability & Accessibility

- Assessment could include attestation, endorsement, testing, voluntary or regulatory-driven certification
- Out of scope: specific clinical content or functionality

Why cMHAFF? What's the Need?

- Target Audience: **mobile health app developers** needing guidance on building apps
- Beneficiaries: consumers, providers, caregivers
- Consumers need protection, transparency and assurance regarding mobile apps. Some examples:
  - What does the app **do**? What **evidence** supports it?
  - What **security** protections exist behind that "cloud?"
  - Can I **comprehend**, or even find, privacy policy and terms of use?
  - Who can the app **share** data with?
  - What does the app **know** about me (location, microphone, camera, contacts, etc.), and what can it **do** on my device?
  - Can I **access** my app data like I can under HIPAA?
  - What happens to my **data** if I delete an app?

cMHAFF January'18 Ballot Results

- **Passed!**
  - 48 Affirmative (30 needed to pass)
  - 0 Negative
  - 57 Abstain
- 79 specific comments
  - 3 NEG (UPDATE: All withdrawn)
  - 76 A-S, A-Q, or A-C
  - **All** comments RESOLVED

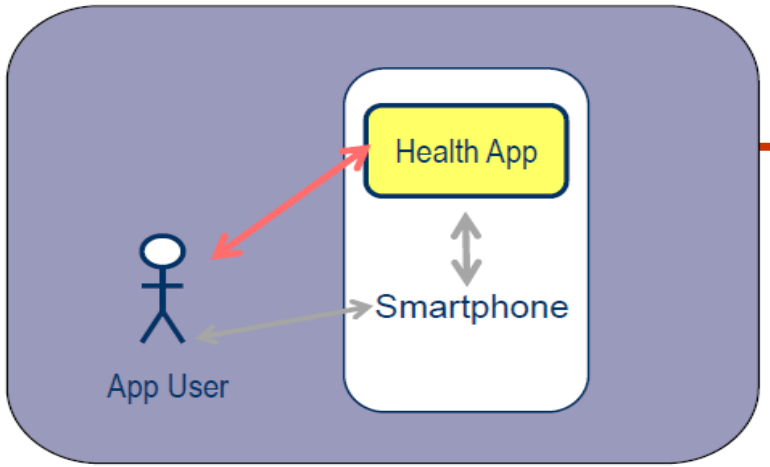
Types of Ballot Comments

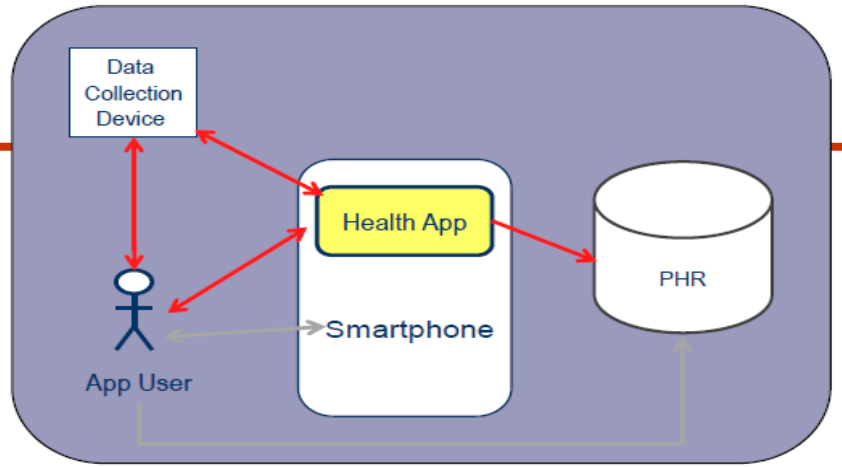
- Clarify ambiguous or confusing wording
- Consolidate similar criteria or moving to different section
- Recommend changes to conformance strength (e.g., SHOULD to SHALL or vice-versa)
- Recommend more specificity (e.g., data elements)
- Remove burdensome or un-actionable items
- Question about audience (developers vs consumers)
- Recommend more precise definition of app categories

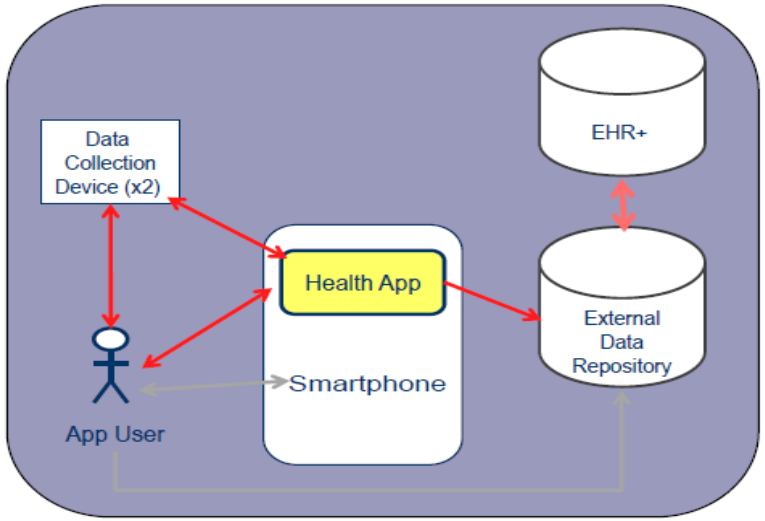
Changes Since September'17

- Incorporation of remaining ballot comment dispositions
- Proposed Consumer Information Label
- Expanded Glossary
- Expanded and reorganized References
- U.K. PAS277 Guidelines (recommended in Sept'17 WGM)
- EU Regulatory Landscape Overview
- End-to-End Review

cMHAFF Exemplar Use Cases







	Simple	Device Integrated	EHR Integrated
FDA App Categorization	wellness	wellness	medical
Device Data Collection	none	unregulated device	FDA regulated device
PHI Data Storage	smartphone	smartphone/PHR	cloud/EHR
Data transmission by App	none	device-app-PHR	device-app-cloud-EHR
Importance of Data Integrity	low	mid	high
HIPAA covered?	no	no, but yes, if white-labeled	yes

EHR-Integrated Use Case "C"

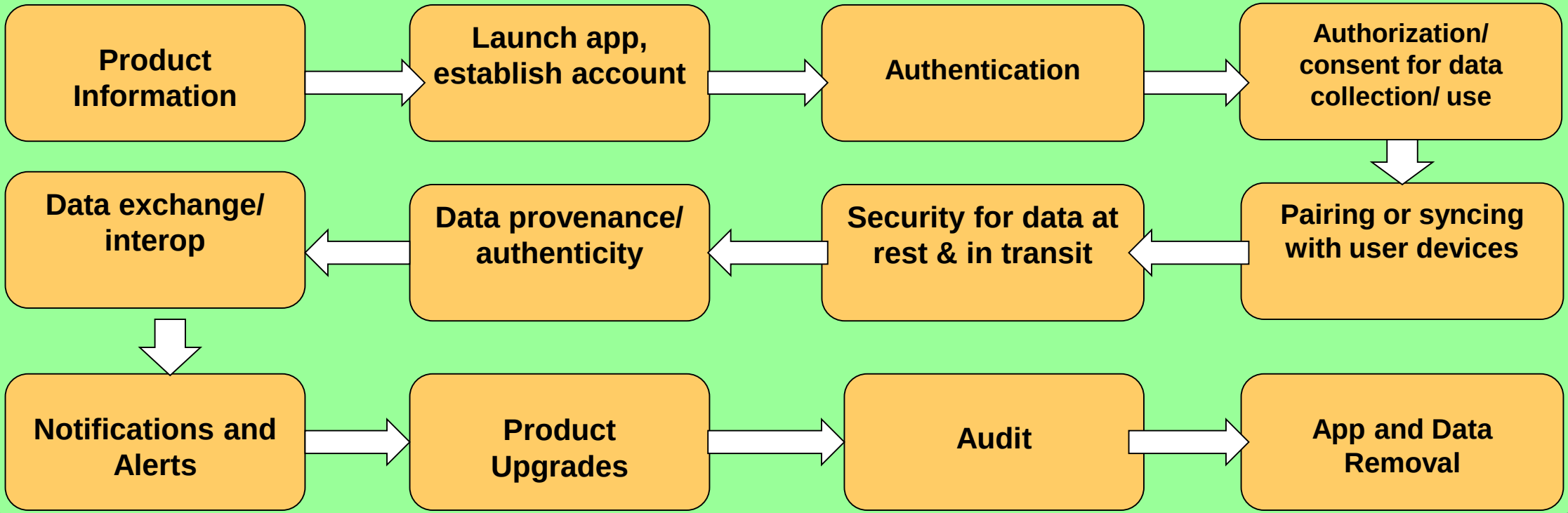
A diabetes management app allows a consumer to collect blood sugar readings through a Bluetooth-enabled glucometer. A healthcare provider offers the app to enable the patient's blood sugar to be captured through devices, rather than relying on manual entry by the patient, and to electronically transmit the readings to the patient's physician, rather than using paper or FAX. Activity data are collected through an activity tracker, and a consumer can open the app to record meals and snacks to enable estimates of caloric consumption. Collected data is automatically "pushed" to a third-party cloud-based platform. The patient is aware of the cloud, though not familiar in detail with how data are protected in transit or storage. When a consumer views information in the app, which shows daily glucometer readings and related information, this information is "pulled" in but does not persist on the smartphone when the app is closed. It is also possible for the consumer to directly enter blood sugar readings (e.g., if Bluetooth connection is not working). From the cloud platform, consumer information is "pushed" to a provider's Electronic Health Record (EHR), where it is accepted as Patient Generated Health Data (PGHD), according to the preferences of the patient and the policies of the provider. From the EHR, a physician can define logic to assess blood sugar readings such that the consumer is alerted through the app when a measurement is out of range, or when a set number of high or low readings are noted within a prescribed period of time.

cMHAFF Sections and App Life Cycle

App Development and Support

✓ Regulatory Considerations
✓ Risk Assessment and Mitigation
✓ Usability Assessment
✓ Customer Support

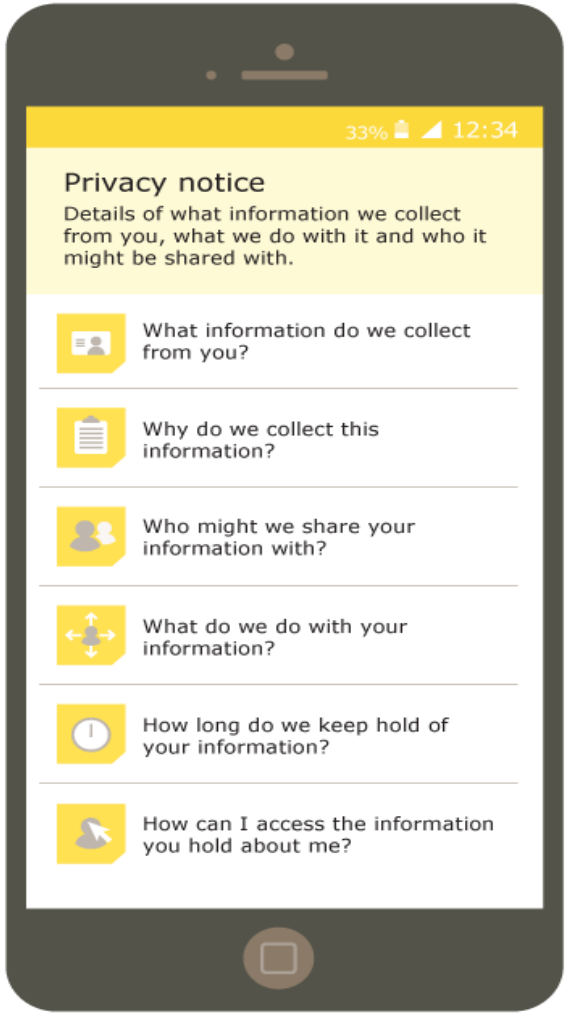
Consumer Use of App



Criteria Example: General Product Info

No.	Strength	Requirement
		GENERAL INFORMATION
G1	SHALL	The description of an app includes the main functionality, the intended use, the intended (target) audience, and potential use of the user's personal data by the app.
G2	SHALL	Screen shots of the app accurately depict the screens of the current version of the product.
G3	SHALL	Product information is provided before the app is used by the consumer, to help consumers decide whether the app is suitable.
G4	SHOULD	The app description clearly states the human languages the app supports.
G5	SHOULD	Provide information about accessibility characteristics in the app description and in contextual assistance sections of the app.
G6	SHOULD	Provide information about the app publisher (persons/organizations) and provide mechanisms to communicate with the publishers
G7	SHOULD	Provide disclosure about sources of funding and possible conflicts of interest for the app (e.g., app use could incent user to buy products or services from app publisher.

Informing Consumers

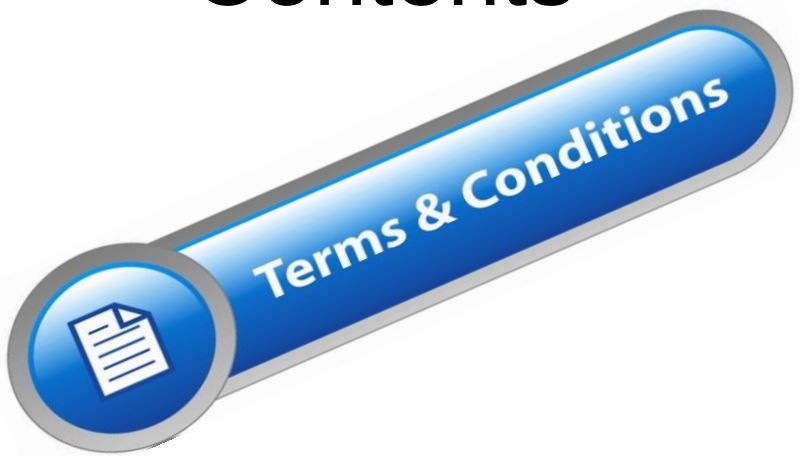


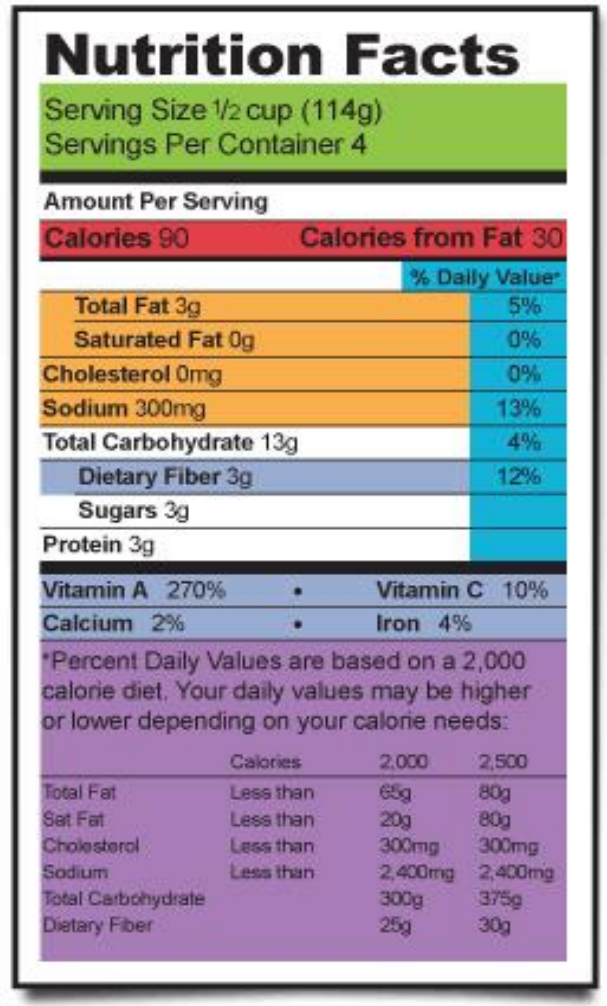
Disclosures

Evidence

Limitations

Contents





Nutrition Facts

Serving Size 1/2 cup (114g)
Servings Per Container 4

Amount Per Serving	
Calories 90	**Calories from Fat** 30
	% Daily Value*
Total Fat 3g	5%
Saturated Fat 0g	0%
Cholesterol 0mg	0%
Sodium 300mg	13%
Total Carbohydrate 13g	4%
Dietary Fiber 3g	12%
Sugars 3g	
Protein 3g	

Vitamin A 270%	•	**Vitamin C** 10%	
Calcium 2%	•	**Iron** 4%	

*Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

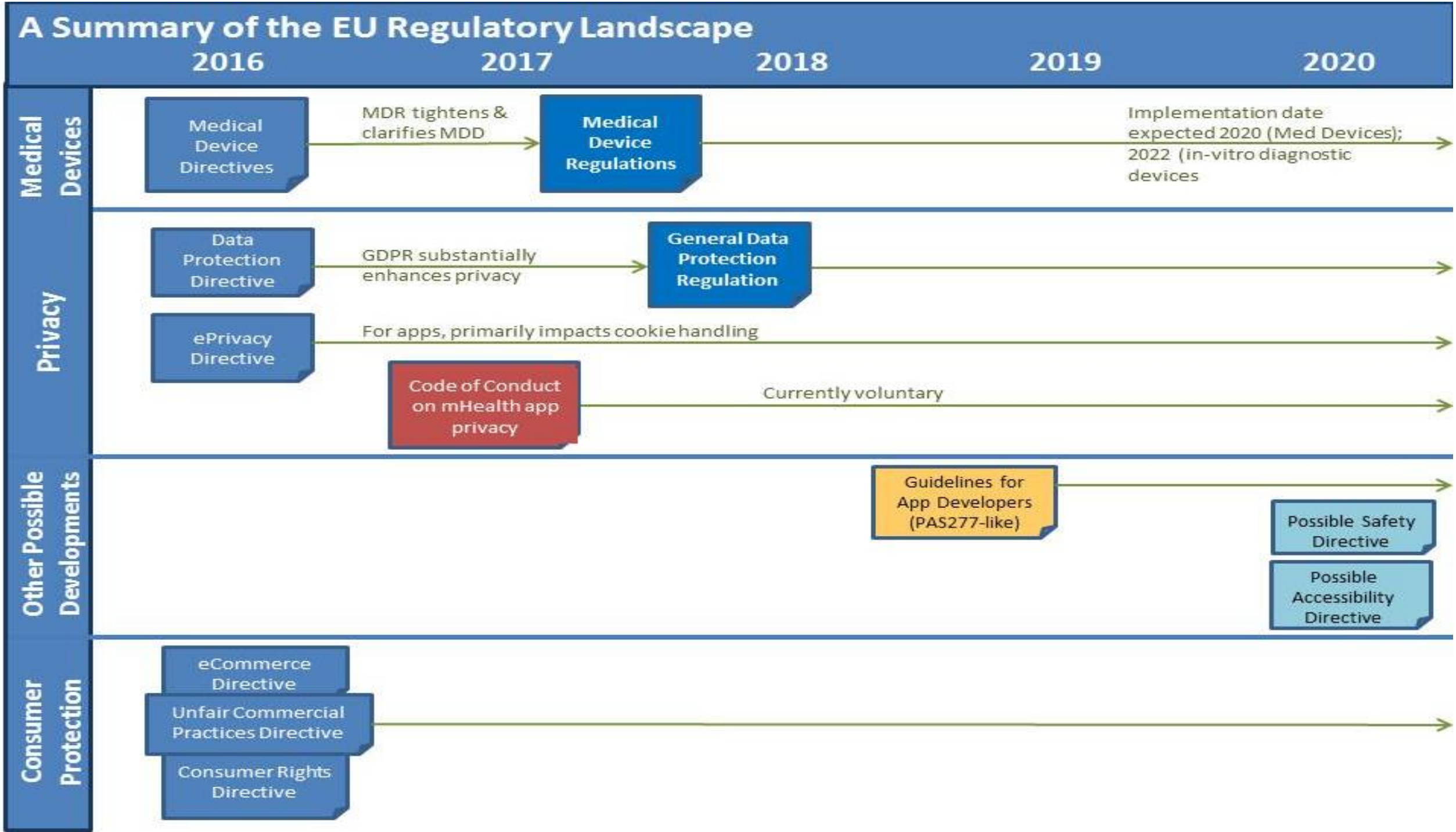
	Calories	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	80g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

European Guidelines Assessed

- French mHealth Good Practice Guidelines
- German Mobile Health Assessment Criteria
- Andalusian App Recommendations
- U.K. PAS277 Quality Criteria
- Finland PHR Cert Criteria
- Other EU initiatives







A Summary of the EU Regulatory Landscape
2016
2017
2018
2019
2020
Medical Devices
Medical Device Directives
MDR tightens & clarifies MDD
Medical Device Regulations
Implementation date expected 2020 (Med Devices); 2022 (in-vitro diagnostic devices
Privacy
Data Protection Directive
GDPR substantially enhances privacy
General Data Protection Regulation
ePrivacy Directive
For apps, primarily impacts cookie handling
Code of Conduct on mHealth app privacy
Currently voluntary
Other Possible Developments
Guidelines for App Developers (PAS277-like)
Possible Safety Directive
Possible Accessibility Directive
Consumer Protection
eCommerce Directive
Unfair Commercial Practices Directive
Consumer Rights Directive

Related U.S. & Global Industry Efforts

ONC ISA Task Force and PGHD Whitepaper

OWASP Mobile Top 10 Security Risks

FTC/FDA/OCR Mobile App Developer Guidance Tool

cMHAFF Invitation: Join us!

- It's a major opportunity in an exploding space: get in on the ground floor!
- Action is under way around the world – people are ready!
- Passed January 2018 STU ballot: on its way to STU!
- Help HL7 collaborate well with the public and private sectors
- Stay connected via HL7 Mobile Health listserv

Project and Contact Info

- cMHAFF meetings are Thursdays at 3pm Eastern
  - Web Meeting
    - WebEx Link: https://westat.webex.com/westat/j.php?MTID=mdd11dffddaca42a8a5625535b49fc3bd
  - Phone 770-657-9270, passcode 465623
- Project Lead: Nathan Botts
- **Join us** to publish and start using cMHAFF!