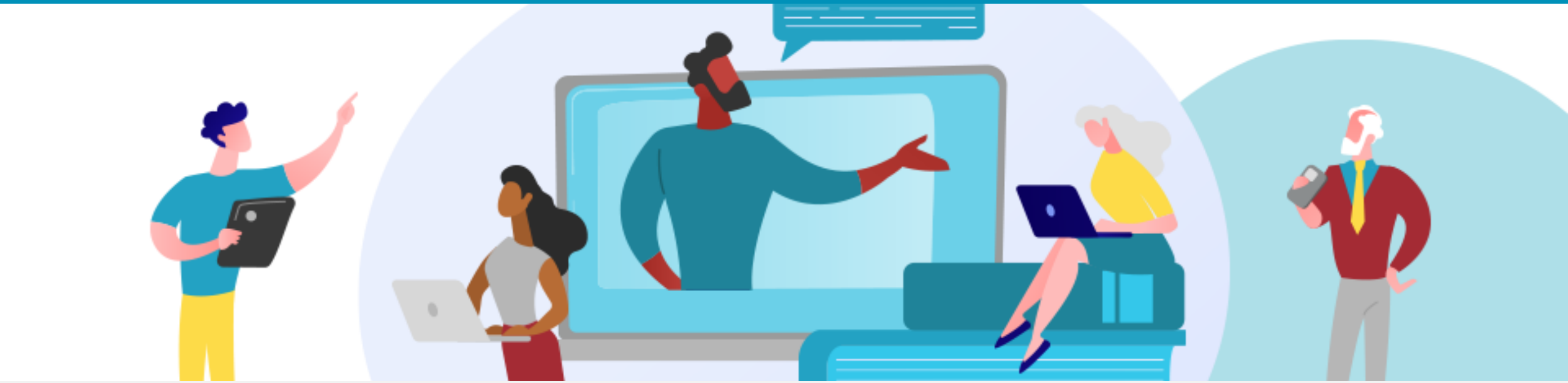
IEEE 11073-10206 - a FHIR Compatible Model for Personal Health Devices

Erik Moll, Philips



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Who am I?

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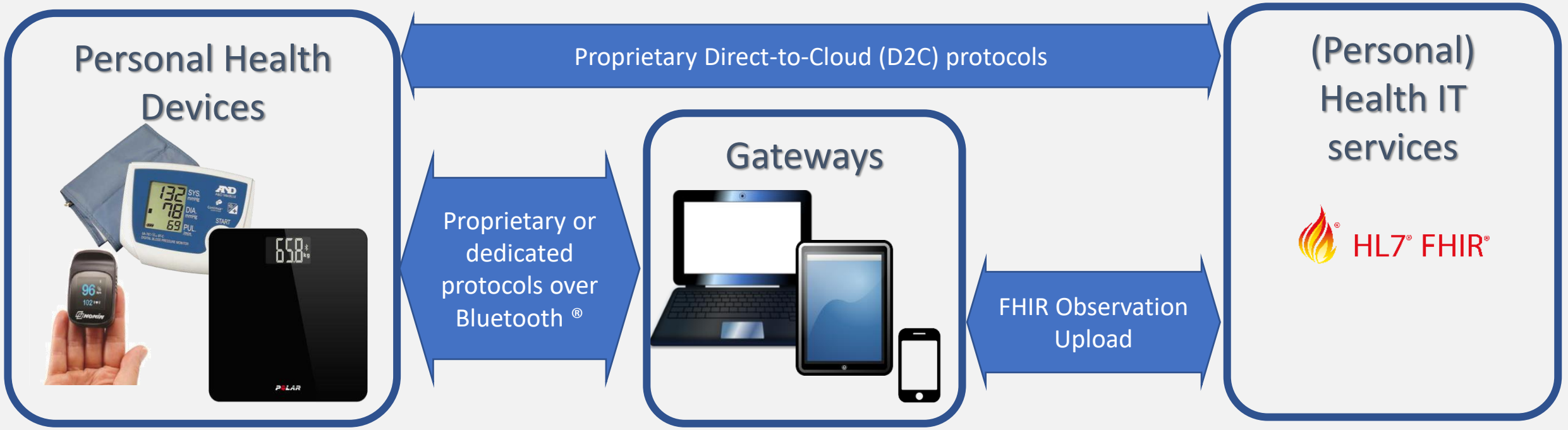
Learning Objectives Tutorial/Let's Build

- Introduce the new IEEE 11073-10206 "ACOM" specification
  - a FHIR Compatible Model for Personal Health Devices
- Explain the background of this work and why this matters for FHIR developers

What is ACOM?

- The problem: today there is still no ***good, generic, interoperable standard solution for personal health / healthcare sensor communication***.
- ACOM is a new IEEE specification that aims to solve this problem by combining the best ideas of many places:
  - ACOM defines an abstract content **model** based on the **IEEE 11073** Domain Information Model (DIM) and **nomenclature** (-10101).
  - Its objects and attributes can easily be presented as **HL7 FHIR resources**.
  - It can be carried in a binary presentation over **Bluetooth LE**.
  - It can be used by cellular **IoT** health sensor devices (binary or JSON)
- Within various working groups of IEEE, IHE and the Bluetooth SIG we're developing the ACOM specification and protocols using it.

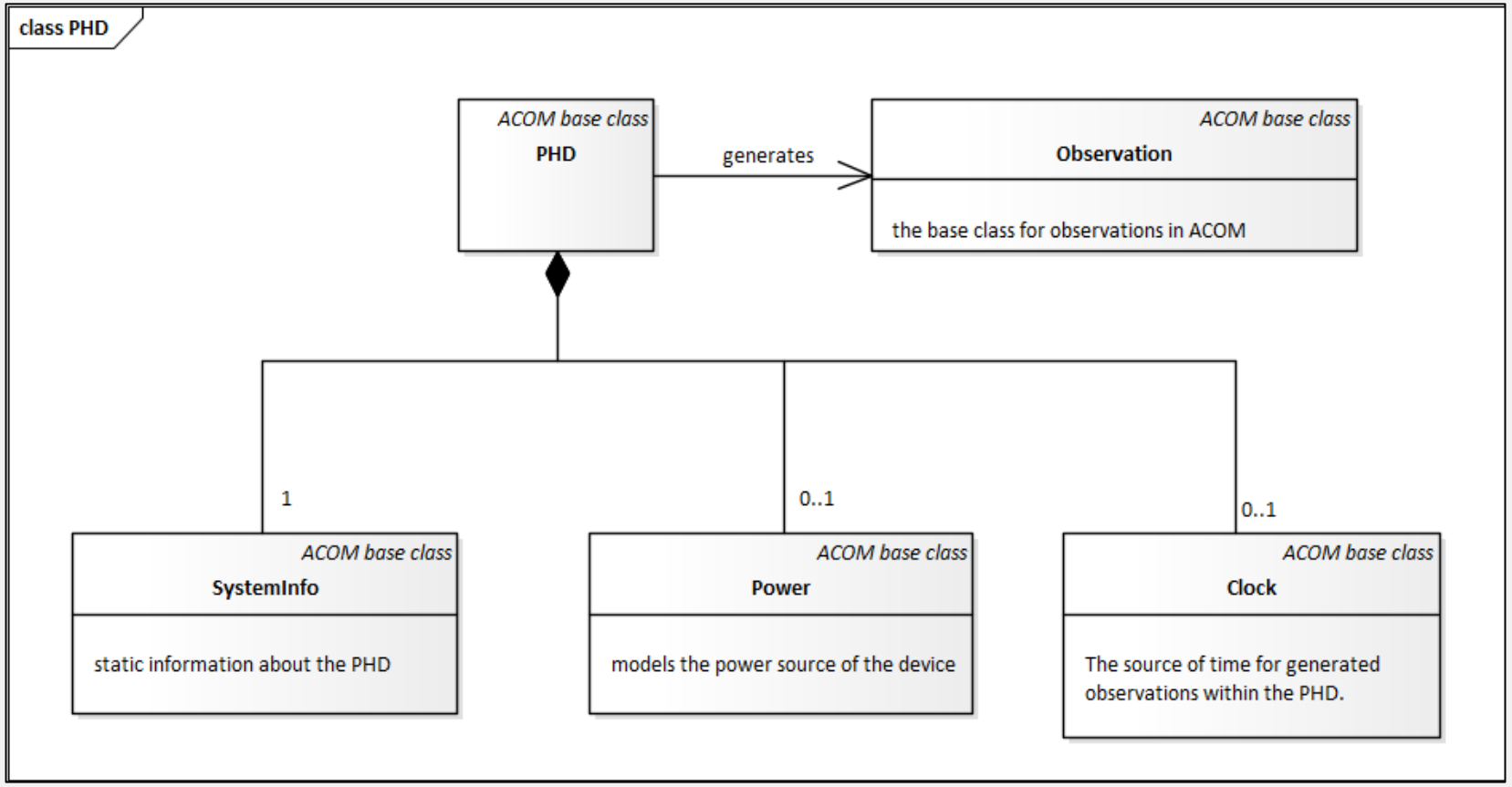
Why is ACOM needed? To make device interoperability as easy as possible!



- Today Personal Health Devices (PHDs) often use proprietary or dedicated protocols to communicate with gateways or services:
  - Bluetooth SIG's GATT profiles are defined per device type
  - PCHA/Continua guidelines based on IEEE 11073-20601 did fail to find market traction
  - Vendors define their own protocols, e.g., to support proprietary features or for marketing reasons
- Hence gateways, that upload the observations to (HL7 FHIR) backend servers, must cope with this diversity, which makes them expensive to develop, maintain and deploy
- For Direct-to-cloud PHDs there is no good compact application protocol defined yet.
- So, we need an equivalent of FHIR suitable for constrained personal health devices – a standard resource model & protocols

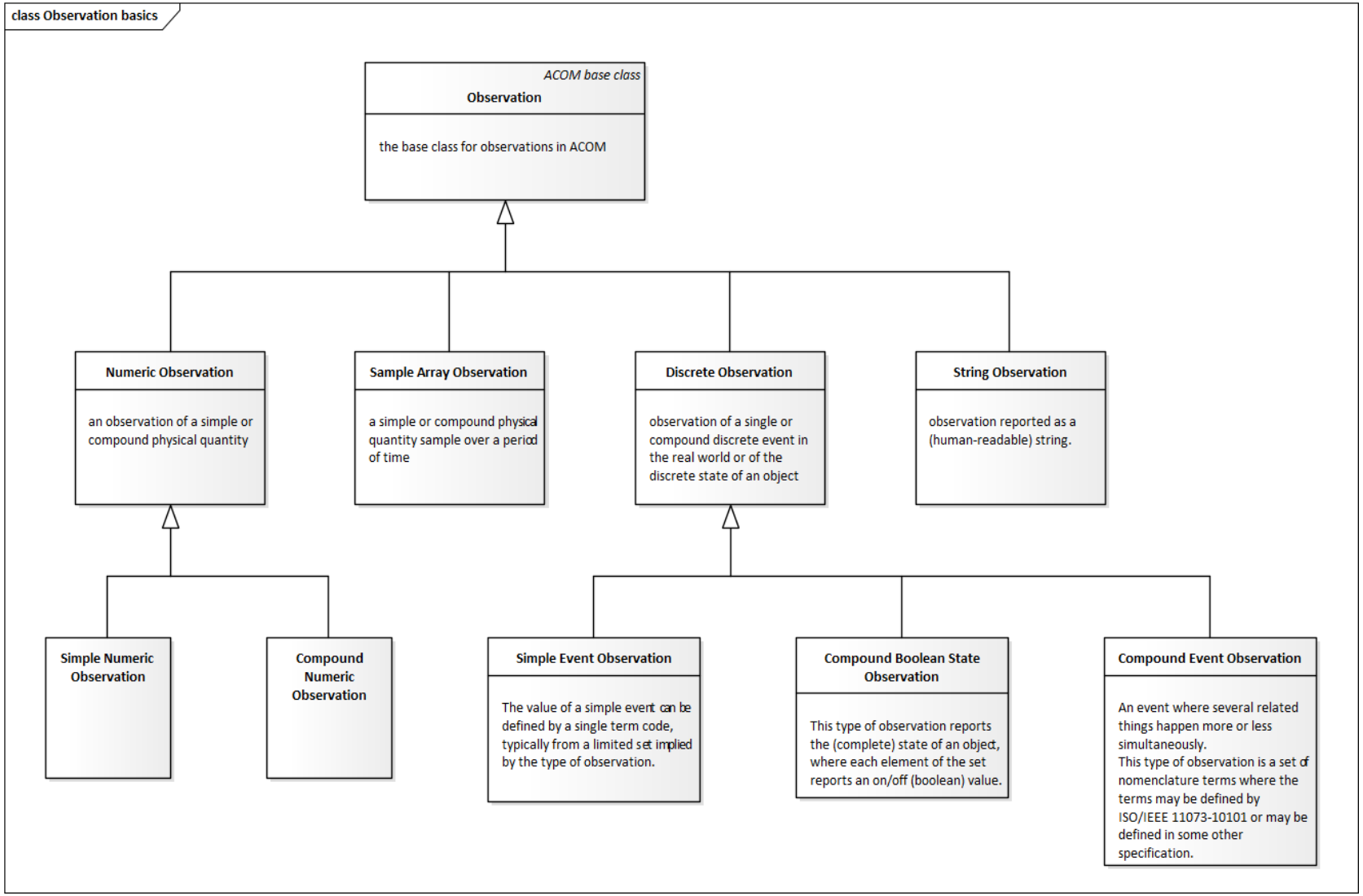
IEEE 11073-10206 - ACOM basics

- ACOM defines a simple information model for PHDs



ACOM Observations

- ACOM supports most common types of observations from PHDs



ACOM Observation details

- Generic base class for all observations
- Mandatory Attributes:
  - Type, Time Stamp,
- Optional attributes:
  - Status, duration, supplemental information (e.g., body site), person ID, derived-from (referenced observation(s)), …
- Subclasses:
  - Numeric, Enumeration, Wave form (real-time sample array), String
- Attribute types are coded themselves as well
  - Only values of attributes differ per type of observation
- Suitable for a compact binary presentation by using IEEE 11073 nomenclature codes

Attribute	Value
TYPE MDC_ATTR_ID_TYPE	defines the type of measurement as defined in the nomenclature (e.g., pulse rate for a specific numeric object instance).
Time stamp MDC_ATTR_TIME_STAMP_ACOM	defines the date and time at the end of the measurement period.
optional attributes	
Period MDC_ATTR_TIME_PD_MSMT_ACTIVE	defines the time duration of the observation period
supplemental info MDC_ATTR_SUPPLEMENTAL_TYPES	may be used to convey supplemental information about the observation. Covers conditions like the location of the sensor or the rate at which the subject reacts to changes.
…	

ACOM Observation example

- Every ACOM object attribute has a type and a value
- For the attribute values IEEE nomenclature codes are used where appropriate
- A protocol can use a code from the IEEE nomenclature specification for the attribute type

Numeric: SpO_2 Observation

Attribute	Value	Binary presentation size in bytes
TYPE MDC_ATTR_ID_TYPE	MDC_PULS_OXIM_SAT_O2	4
Unit Code MDC_ATTR_UNIT_CODE	MDC_DIM_PERCENT	2
Observed Value MDC_ATTR_NU_VAL_OBS	89.0	4
Time stamp MDC_ATTR_TIME_STAMP_ACOM	2017-09-04 16:30:00 +1:00	8
optional attributes	E.g.: supplemental info: Spot-check MDC_ATTR_SUPPLEMENTAL_TYPES: MDC_MODALITY_SPOT	9
Total size		27

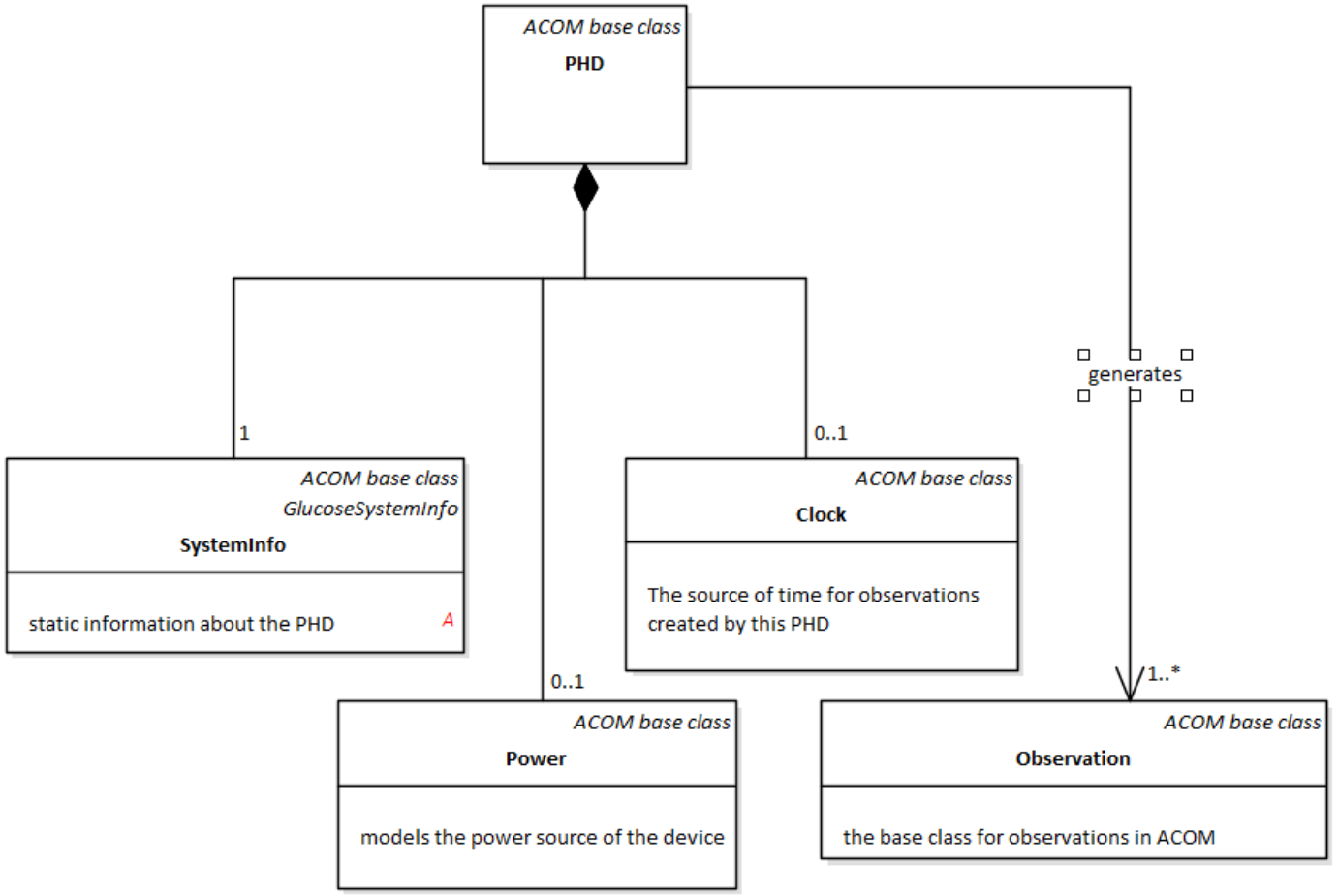
ACOM Mapped to FHIR

- Example ACOM & FHIR SpO2 Observation
- Mapping is following the HL7 FHIR PHD Implementation Guide and the IHE PHD Observation Upload (POU) profile

ACOM Observation attribute	Value	FHIR Observation attribute & value
Object	Numeric Observation	{ “resourceType”: “Observation”,
Type	MDC_PULS_OXIM_SAT_O2 (2::19384)	“code”: {“coding”: [{ “system”: “urn:iso:std:iso:11073:10101”, “code”: “150456” }]},
Unit Code	MDC_DIM_PERCENT (4::544)	“valueQuantity”:{ “system”: “urn:iso:std:iso:11073:10101”, “code”: “262688”, “value”: 89.0 },
Observed Value	89.0	
Time stamp	2017-09-04 16:30:00 +1:00 (1504542600)	“effectiveDateTime”: “2017-09-04T16:30:00+01:00” }

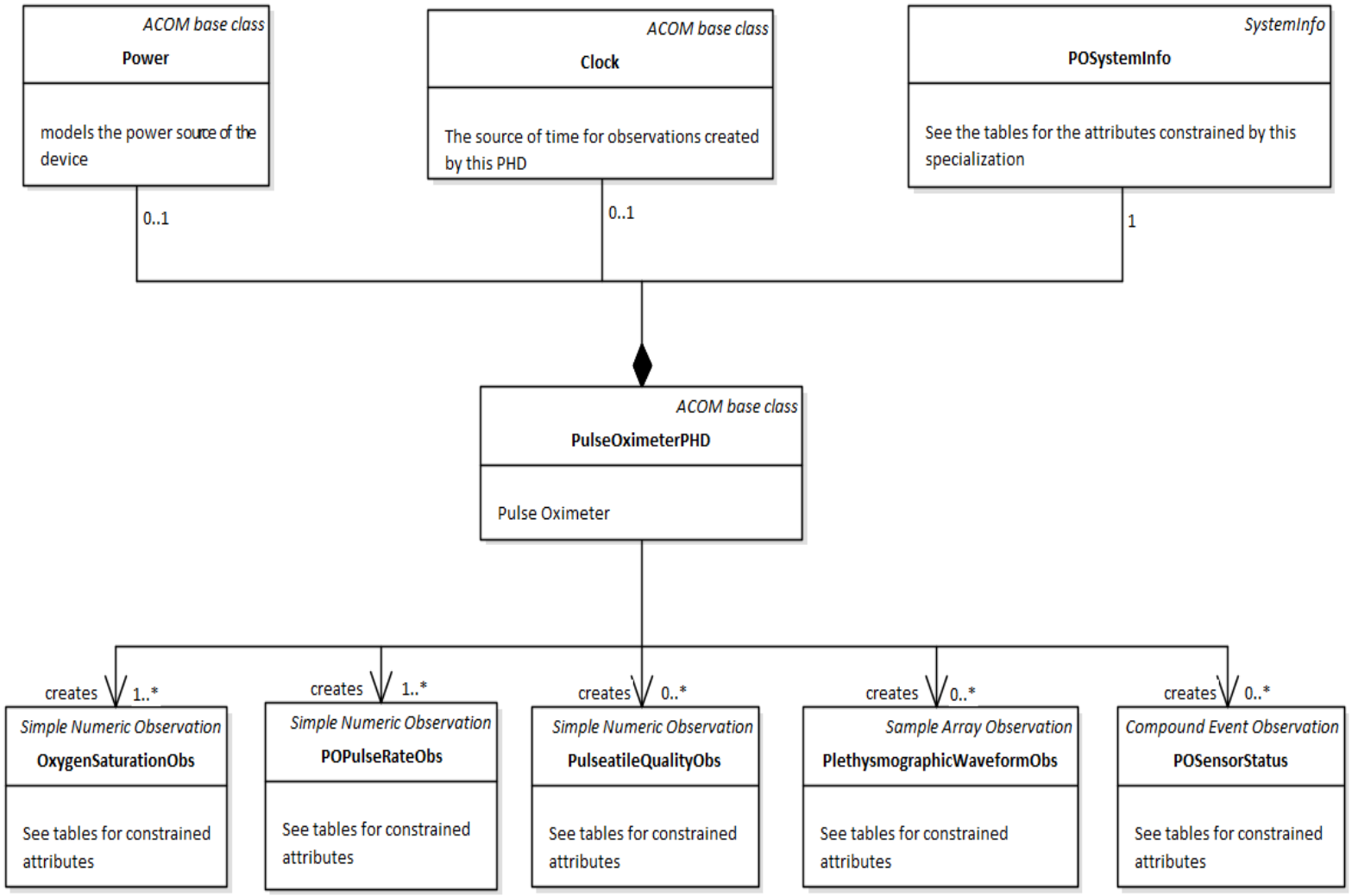
The ACOM PHD class

- Composed of a SystemInfo, Power and Clock Object
- Generates Observations
- The SystemInfo contains static information defining the PHD:
  - Device identification attributes (serial number, UDI, EUI-64)
  - The types of Observations (heart rate measurement, blood pressure measurement) the PHD can generate
  - The supported device specializations (weight scale, blood pressure monitor, …)
  - …
- Maps to a FHIR Device resource



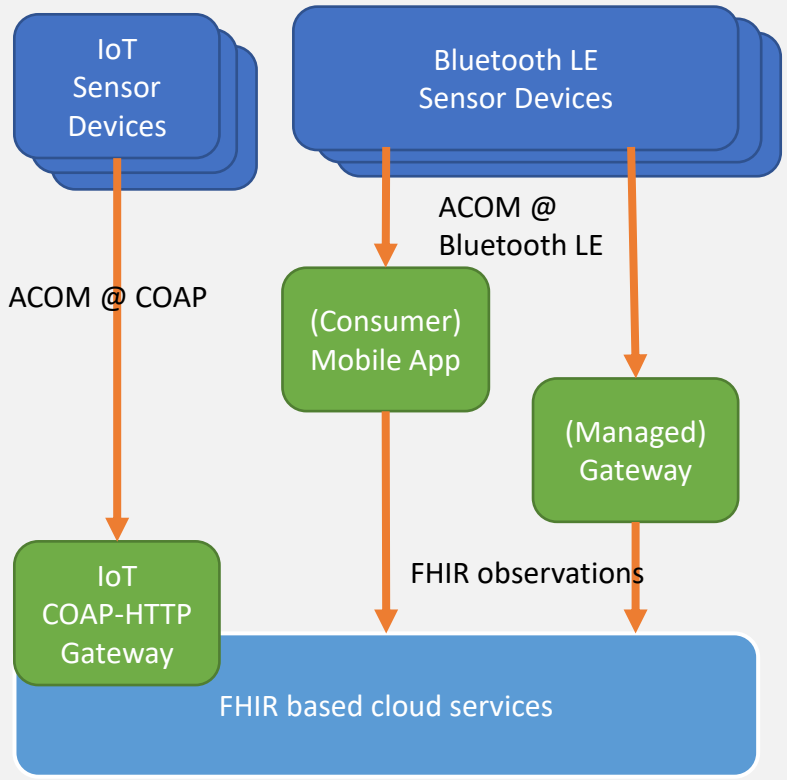
Device Specializations

- Define a set of coherent Observation subclasses that a type of PHD shall or may supports.
- E.g., a PulseOximeter shall be able to generate OxygenSaturation and PulseRate Observations
- It may also generate PulsatileQuality, PlethysmographicWaveform and SensorStatus Observations.
- All existing IEEE 11073-20601 device specializations are supported.



Reasons to adopt / support ACOM

- Build once
  - ACOM enables a generic solution to connect sensor devices to apps, gateways and to cloud services
- Flexible solution
  - Sensor types can be added without coding
  - The set of supported Observations can be extended without coding
  - Many device specializations are available
- Directly maps to FHIR resources
  - Usable across healthcare eco-system
  - Suitable for [personal] health sensor devices at home and elsewhere



Status of standards development

- The ACOM model is being specified in the IEEE PHD workgroup (IEEE 11073-10206)
  - Taking the best of existing IEEE 11073 specifications: the domain information model and the nomenclature definitions
  - A **first complete draft is ready**, and the initial ballot has just finished. Aiming for an approved version Q2/Q3 2021.
- The Generic Health Sensor profile and service are being defined in the Bluetooth SIG
  - The Medical Devices workgroup has defined requirements for a **Bluetooth LE GATT-based profile and service** to communicate the ACOM objects.
  - We aim for a Bluetooth SIG GATT service & profile prototyping specification in 2021. Adoption early 2022.
  - Currently working on an 0.5 design of the GHS Service and Profile.
- The IHE PCH domain is working on an **IHE Direct-to-Cloud profile** for constrained cellular-connected sensor devices
  - This profile is based on ACOM
  - We're discussing the use of a JSON or binary format for ACOM content here and investigating how security aspects can be dealt with.

- For further information contact IHE PCH or PCHA, IEEE, …
  - https://wiki.ihe.net/index.php/Personal_Connected_Health
  - http://www.pchalliance.org/
  - https://standards.ieee.org/project/11073-10206.html

0.5 Design phase of GHS in the Bluetooth SIG

- Topics being covered:
  - Observation characteristic(s) structure
  - Use of RACP for storing & retrieving under collector control
  - Message flow for typical observation upload scenarios
  - Design of timestamp and clock / current time management
  - DIS including UDI, Power / Battery status

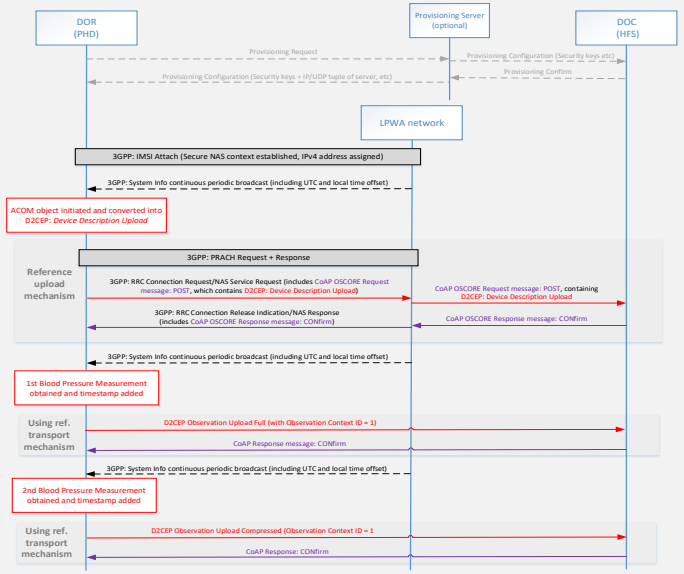
Supporting companies

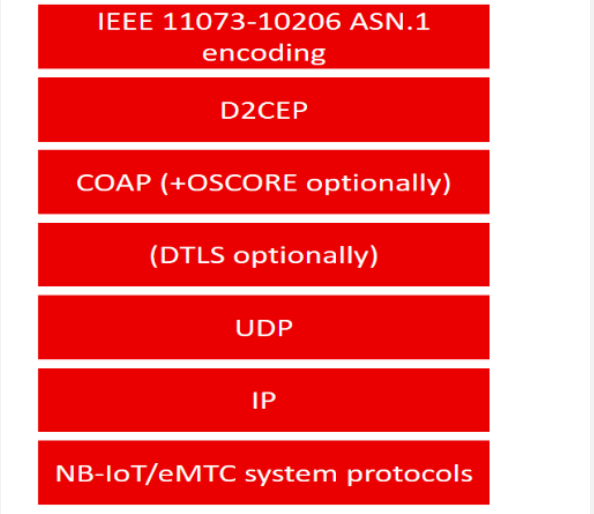
Philips
Braveheart Wireless
Code Blue Communications
Chongqing University
A&D Medical
Lamprey Networks (LNI)
Nonin Medical
Selekt Bilgisayar (Turkey)
(Roche)

- For more details: join the Bluetooth SIG Medical Devices working group

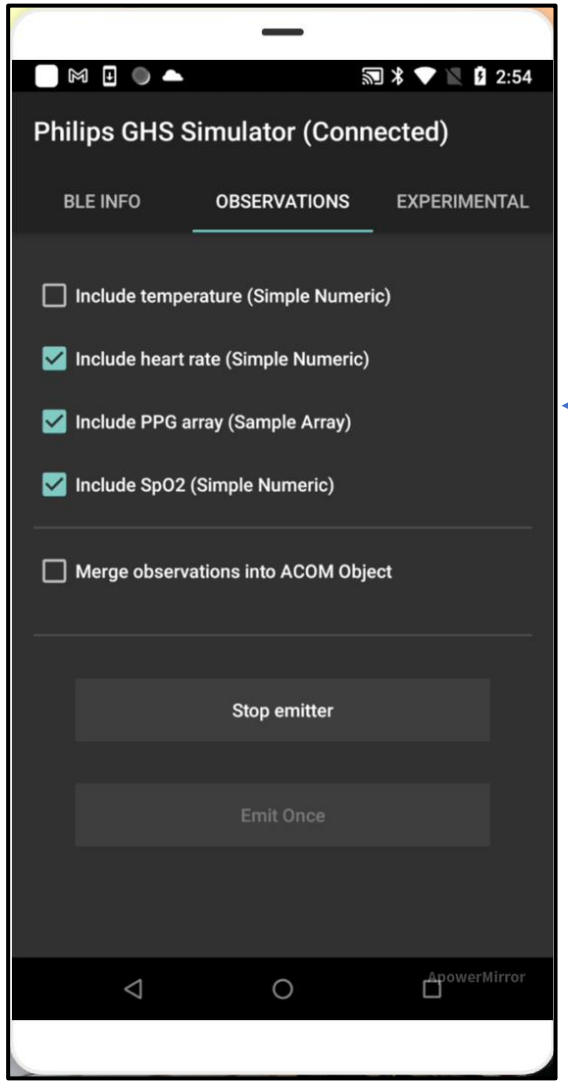
D2C profile development in IHE

- Ongoing work in the IHE PCH sub-domain
- Contributors: Vodafone, Medisante, Roche, Philips
- Topics:
  - Protocol stacks – COAP being a main candidate
  - Payload format – JSON(FHIR) or binary
  - Security – BEST, OSCORE are being considered





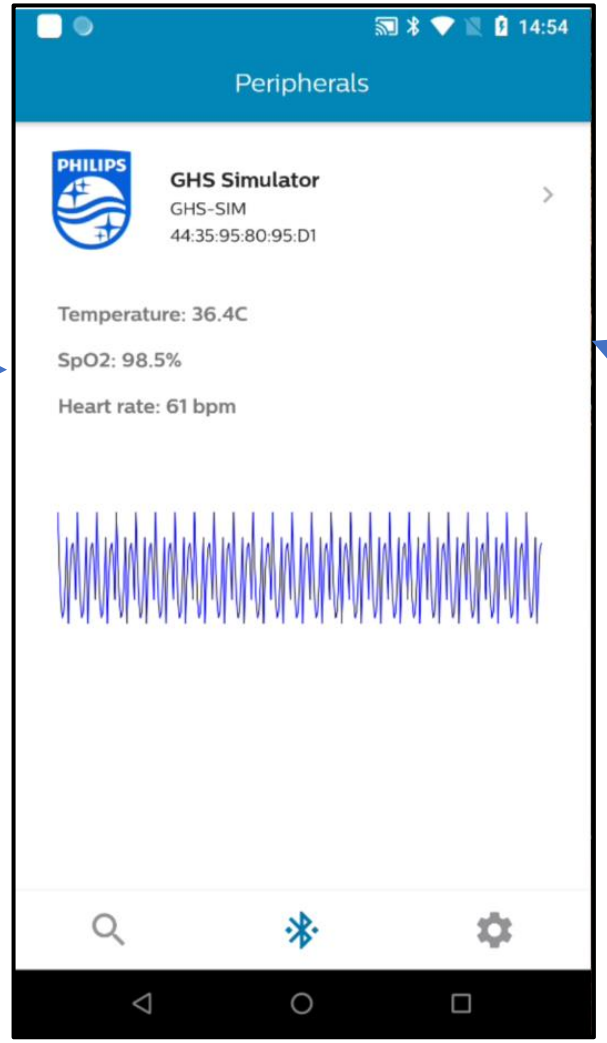
Demonstrations – GHS prototypes (1)



Bluetooth®

LE / GATT / GHS

- Health Observations
- Device information
- Time and power information



HL7 FHIR

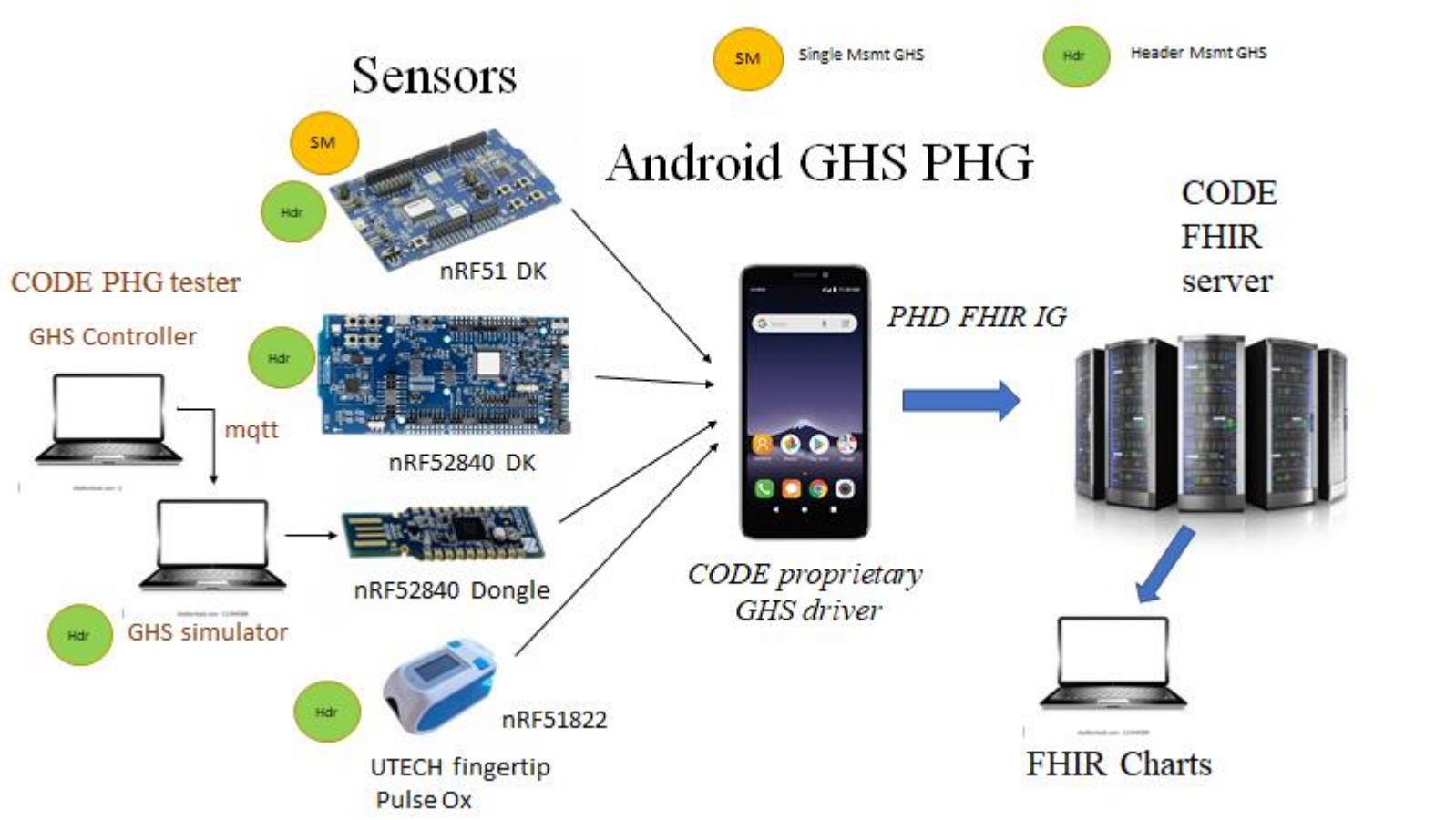
Post Observations

Open-sourced

https://github.com/philips-labs/BLE-GHS-Server-Simulator

Demonstrations – GHS prototypes (2)

- PCHA CODE project
  - Initiative to have quality code available following the PCHA interoperability guidelines
  - Includes Personal Health Gateway (PHG) supporting ACOM over Bluetooth LE (GHS) & much more
  - Plan is to move to OSS in the future



What did you learn?

- We introduced the IEEE Abstract Content Model for Personal Health Devices - ACOM
  - It defines a generic model for personal health devices and the observations these devices can generate
  - The objects in this model can easily be mapped to FHIR resources
  - A Bluetooth GATT service and profile based on ACOM are under development
  - In IHE a profile for Direct-to-Cloud sensor devices using ACOM is being defined
  - It enables build-once gateways to get PHD Observations into FHIR servers
  - Early demonstrators / source code is available

Contact

- During DevDays, you can find / reach me here:
  - Via Whova App – Speaker's Gallery
  - Email:
    - Erik Moll - erik.moll@philips.com (Bluetooth GHS spec lead)
    - Barry Reinhold - barryreinhold@lnihealth.com (IEEE ACOM spec lead)
    - Brian Reinhold – brianreinhold@lnihealth.com (CODE demo)
    - Thom Ericksson - thom.erickson@himss.org (HIMSS/PCHA sponsor)
    - Abdul Nabi – abdul.nabi@philips.com (Philips demo)

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Q&A

- Questions are welcome!

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