UMANA PERSONE

IMPRESA SOCIALE RICERCA E SVILUPPO

CASA SOLLIEVO DELLA SOFFERENZA • SAN GIOVANNI ROTONDO •

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Ethics Session

Italian Pilot

Gianna Vignani- Training and Data Manager (UP)
Francesco Giuliani - Training and Data Manager (CSS)

Florence, 30 – 31 March 2022

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857188

UP Tuscany

Italian Pilot

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WP10 Tasks

Ethics, Privacy and Data Protection activities timeline

Material for user enrolment
- Procedure to **recruit**
- Drafting of personalized and simplified **documents**
- **Training** of “facilitators”
- Signature of **JCA** between UP and each cooperative

SEPTEMBER 2021

OCTOBER - NOVEMBER 2021

Open discussion about DPA
- Coordination between UP-CSS to find a **common solution**
- **collecting experience** on this topic from other LSP (ADLIFE Project)

Finalization of the Agreements
- Definition of JCA contents and **signature** with tech partners
- First release of **Cybersecurity Questionnaire**

DECEMBER 21-JANUARY 22

FEBRUARY- MARCH 22

Refinement for deployment
- Submission of the requests to the **Ethical Committee**
- 3 internal meetings to check the Privacy Compliance of the wristband - Definition of a **common strategy**

WP10 Tasks

Main outcomes

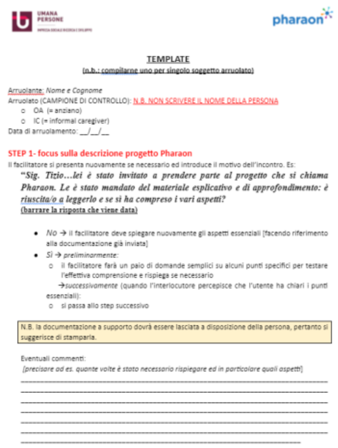
- ✓ "**Roadmap**" for the enrolment – unstructured interview:
  - Manage enrolment sessions properly and standardize a common procedure
  - Help facilitators to understand the effectiveness of communication
  - Verify the level of accessibility of privacy notes
- ✓ Personalization of privacy notes according to the user target – **simplified privacy note** (national authority contest)
- ✓ First release of the **DPIA** for Fitbit in the monitoring scenario
- ✓ Coordination of a group of 9 people appointed by cooperatives, including 4 experts (DPO, ICT and GDPR experts) – **Privacy by Design culture**
- ✓ **Open and stable discussion** within the Italian pilot about ethical problems

1) Roadmap


ROADMAP PER L'ARRUOLAMENTO UTENTI

CAMPIONE DI CONTROLLO

ACCORGIMENTI PRELIMINARI

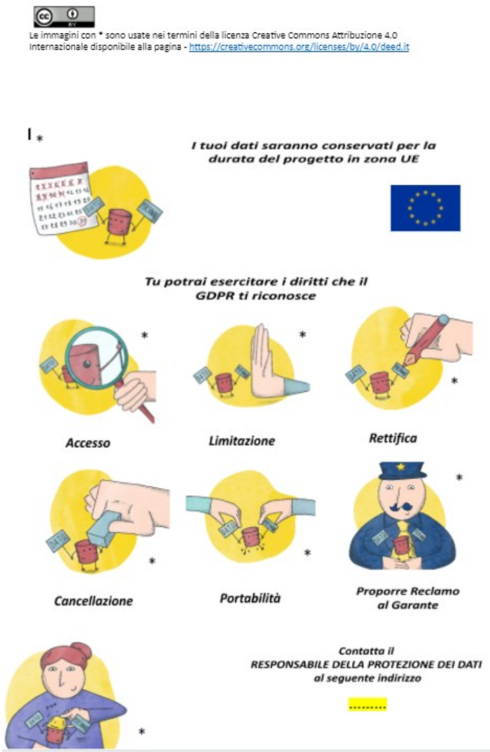

TEMPLATE

STEP 1- focus sulla descrizione progetto Pharaon

2) Privacy note with icons


INFORMATIVA SEMPLIFICATA SUL TRATTAMENTO DATI PERSONALI

SCENARIO SOCIALIZZAZIONE E STIMOLAZIONE



WP10 Tasks

Goals to be achieved

- Finalization of JCA with missing partners
- Questionnaires management
- Ethical Committees amendment requests (Open Call)
- DPIA final version (monitoring scenario) and definition of a common improvement plan according with tech partners
- DPIA first version (socialization and stimulation scenario – telepresence)
- Enhancement of facilitators training programme
- Definition of some internal procedures: Data Breach Management; Exercise of Subject’s Rights

Focus on

Internal discussion about DPA

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Why Joint Controllership Agreement – art. 26 GDPR?

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- Relevant legislation: Guidelines n. 7/2020 EDPB (general); Grant Agreement and Consortium Agreement (special)
- Two different approaches: «*purposes and means*» at pilot level Vs «*purposes and means*» at consortium level
- Two different consequences: Data Controller-Data Processor Agreement – art. 28 GDPR - Vs Joint Controllership Agreement – Art. 26 GDPR
- Advantages of the second option: more distribute liability for data controllers; pushing all partners involved to increase their accountability level
- Disadvantage: unrepeatability of the solution at the termination of Grant Agreement and Consortium Agreement
- Final solution is to use a **modular and flexible approach:**

1. Starting with JCA
2. Exploiting the experience of the pilot deployment to:

- Increase the awareness of the use of tech solution and privacy protocols (mainly for social care providers)
- Demonstrate the level of their accountability (mainly for tech providers)

3. Defining terms of the Agreement art. 28 GDPR before the end of the project

CSS Apulia

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WP10 Tasks

Ethic, Privacy and Data Protection

MAY 2021

Approval of the study protocol by the CSS Ethical Committee

OCTOBER - NOVEMBER 2021

Material for user enrollment

- Standardization of the procedure to recruit participants
- Preparation of the materials for user enrollment (Informed consent, Privacy Note and consent to data processing)

DECEMBER 21-JANUARY 22

Definition of Data Processing Agreements and signature with involved partners

FEBRUARY- MARCH 22

- **Meetings to check the Privacy Compliance of the wristband alternatives**
- **DPIA**

Getting ready for new technologies following Open Call results

Focus on

Wristband and Privacy issues

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Experience with MaxHealthBand (Pre-Validation)

Advantages

- ✓ Direct data exchange with IoTool without the need to go to the cloud to gather data from the device

Drawbacks

- ✓ Battery life. In many cases of normal use the battery did not last for an entire day
- ✓ Need to reconfigure it before a full battery charge
- ✓ Unreliability of measurements (specifically heart rate)
- ✓ Need of specific technical effort to build parameters and variables needed for the piloting activities (steps, sleep, etc.) from the raw data produced by the device
- ✓ Price well above off-the-shelf and more advanced devices available in the market

Comparison between other wearables devices

- ✓ The WearOS based devices are affected by short battery life and they were tested by technical partners only for Heart Rate measurements. Furthermore, their price is high.

- ✓ The PineTime64 model is affected by short battery life too, problems in detecting heart rate and not all parameters are accurate. Moreover, it is going out of stock.

- ✓ The configuration of Xiaomi bands, according to the experience of technical partners, are strictly dependent on firmware updates/versions as one has to develop a specific integration module for each version of the firmware. This can imply difficulties in managing possible upgrades with respective delays due to necessary unforeseen development activities.

Bibliographic Evidence about FitBit use for Life style tracking

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Article Reference	Conclusions
Shcherbina, A.; Mattsson, C.M.; Waggott, D.; Salisbury, H.; Christle, J.W.; Hastie, T.; Wheeler, M.T.; Ashley, E.A. **Accuracy in Wrist-Worn, Sensor-Based Measurements of Heart Rate and Energy Expenditure in a Diverse Cohort**. J. Pers. Med. 2017, 7, 3. https://doi.org/10.3390/jpm7020003	Fitbit Surge ranks third in Heart Rate (HR) accuracy measurement with respect to Apple Watchs (first) and Microsoft Band (second). The Fitbit device ranks first in terms of error in expressing Energy Expenditure in terms of calories with respect to the other devices. Six of the reviewed devices achieved a median error for HR below 5% during cycling. No device achieved an error in EE below 20 percent. The Apple Watch achieved the lowest overall error in both HR and EE, while the Samsung Gear S2 reported the highest.
Modave F, Guo Y, Bian J, et al. **Mobile Device Accuracy for Step Counting Across Age Groups**. JMIR Mhealth Uhealth. 2017;5(6):e88. Published 2017 Jun 28. doi:10.2196/mhealth.7870	Results: Among the 60 participants, 36 were female (60%) and 54 were right-handed (90%). Median age was 53 years (min=19, max=83), median BMI was 24.1 (min=18.4, max=39.6). There was no significant difference in left- and right-hand step counts by device. Our analyses show that the Fitbit Surge significantly undercounted steps across all age groups. Samsung Gear S2 significantly undercounted steps only for participants among the 40-64 year age group. Finally, the Nexus 6P significantly undercounted steps for the group ranging from 65-84 years.
Svensson T, Chung UI, Tokuno S, Nakamura M, Svensson AK. **A validation study of a consumer wearable sleep tracker compared to a portable EEG system in naturalistic conditions**. J Psychosom Res. 2019 Nov;126:109822. doi: 10.1016/j.jpsychores.2019.109822. Epub 2019 Aug 30. PMID: 31499232.	Objective: To compare a wearable device, the Fitbit Versa (FV), to a validated portable single-channel EEG system across multiple nights in a naturalistic environment. Results: The FV did not significantly differ from the portable EEG for the measures TIB and TST (Table 2, Table 3, and Fig. 2). However, compared with the portable EEG, the FV significantly overestimated SE (bias: 7.4%), time spent in deep sleep (36.2 min) and wake (25.4 min), and significantly underestimated time spent in light sleep (20.2 min), and REM sleep (7.8 min)
Wu CT, Li GH, Huang CT, Cheng YC, Chen CH, Chien JY, Kuo PH, Kuo LC, Lai F. **Acute Exacerbation of a Chronic Obstructive Pulmonary Disease Prediction System Using Wearable Device Data, Machine Learning, and Deep Learning: Development and Cohort Study**. JMIR Mhealth Uhealth. 2021 May 6;9(5):e22591. doi: 10.2196/22591. PMID: 33955840; PMCID: PMC8138712.	This prospective study was performed at National Taiwan University Hospital. Patients with COPD that did not have a pacemaker and were not pregnant were invited for enrollment. Data on lifestyle, temperature, humidity, and fine particulate matter were collected using wearable devices (Fitbit Versa), a home air quality–sensing device (EDIMAX Airbox), and a smartphone app. AECOPD episodes were evaluated via standardized questionnaires. With these input features, the prediction performance of machine learning models, including random forest, decision trees, k-nearest neighbor, linear discriminant analysis, and adaptive boosting, and a deep neural network model were evaluated
Benedetti D, Olcese U, Frumento P, Bazzani A, Bruno S, d'Ascanio P, Maestri M, Bonanni E, Faraguna U. **Heart rate detection by Fitbit ChargeHR™ : A validation study versus portable polysomnography**. J Sleep Res. 2021 Dec;30(6):e13346. doi: 10.1111/jsr.13346. Epub 2021 Apr 10. PMID: 33837981.	Bland–Altman analysis supports the overall higher accuracy in the detection of HR during sleep. The relatively high accuracy of Fitbit Charge HR pulse rate detection during sleep makes this device suitable for sleep- related research applications in healthy participants, under free- living conditions.
O'Driscoll R, Turicchi J, Hopkins M, Duarte C, Horgan GW, Finlayson G, Stubbs RJ. **Comparison of the Validity and Generalizability of Machine Learning Algorithms for the Prediction of Energy Expenditure: Validation Study**. JMIR Mhealth Uhealth. 2021 Aug 4;9(8):e23938. doi: 10.2196/23938. PMID: 34346890; PMCID: PMC8374660.	The study aims to test the validity and out-of-sample generalizability of algorithms for the prediction of energy expenditure in several wearables (ie, Fitbit Charge 2, ActiGraph GT3-x, SenseWear Armband Mini, and Polar H7) using two laboratory data sets comprising different activities. Results: We believe that this is the first study to classify the intensity of activity using machine learning algorithms in Fitbit devices. In Fitbit models, we demonstrated accuracies up to approximately 78% (κ=0.6), with superior performance observed for sedentary activity and MVPA classifications, but these were generally less accurate than ActiGraph and SenseWear models, where up to approximately 85% accuracy (κ=0.74) was achieved.
Germini F, Noronha N, Borg Debono V, Abraham Philip B, Pete D, Navarro T, Keepanasseril A, Parpia S, de Wit K, Iorio A. **Accuracy and Acceptability of Wrist-Wearable Activity-Tracking Devices: Systematic Review of the Literature**. J Med Internet Res. 2022 Jan 21;24(1):e30791. doi: 10.2196/30791. PMID: 35060915; PMCID: PMC8817215.	Review on 65 published papers. Conclusios: The outcomes assessed most frequently were step counts, heart rate, and energy expenditure. For step counts, the Fitbit Charge (or the Fitbit Charge HR) had a mean absolute percentage error (MAPE) <25% across 20 studies. Conclusions: The Fitbit Charge and Fitbit Charge HR were consistently shown to have a good accuracy for step counts and the Apple Watch for measuring heart rate. None of the tested devices proved to be accurate in measuring energy expenditure.
Farmer C, van den Berg ME, Vuu S, Barr CJ. **A study of the accuracy of the Fitbit Zip in measuring steps both indoors and outdoors in a mixed rehabilitation population**. Clin Rehabil. 2022 Jan;36(1):125-132. doi: 10.1177/02692155211035293. Epub 2021 Jul 27. PMID: 34313149.	The Fitbit Zip shows high step count accuracy with manual step count in a mixed subacute rehabilitation population. However, accuracy is affected by walking speed, with decreased accuracy in limited community walkers.
Nissen M, Slim S, Jäger K, Flaucher M, Huebner H, Danzberger N, Fasching PA, Beckmann MW, Gradl S, Eskofier BM. **Heart Rate Measurement Accuracy of Fitbit Charge 4 and Samsung Galaxy Watch Active2: Device Evaluation Study**. JMIR Form Res. 2022 Mar 1;6(3):e33635. doi: 10.2196/33635. PMID: 35230250.	Although the Fitbit Charge 4 slightly underestimated the HR by −1.66 bpm (bias), the Samsung Galaxy Watch Active2 overestimated the HR by 3.84 bpm (bias). In resting and sedentary activities (seated rest, typing, and laying down) and slow walking, the Fitbit Charge 4 achieved lower absolute and absolute percentage error rates. During standing up and all other physical activities, the Samsung Galaxy Watch Active2 outperformed the Fitbit Charge 4. A particularly high bias (i.e., mean difference) was observed by the Fitbit Charge 4 during standing up (−7.95 bpm) and squats (−12.52 bpm). The Samsung Galaxy Watch Active2's highest bias was measured during typing (8.63 bpm) and laying down on the left side (6.01 bpm).

Variables of interest measured by the FitBit device

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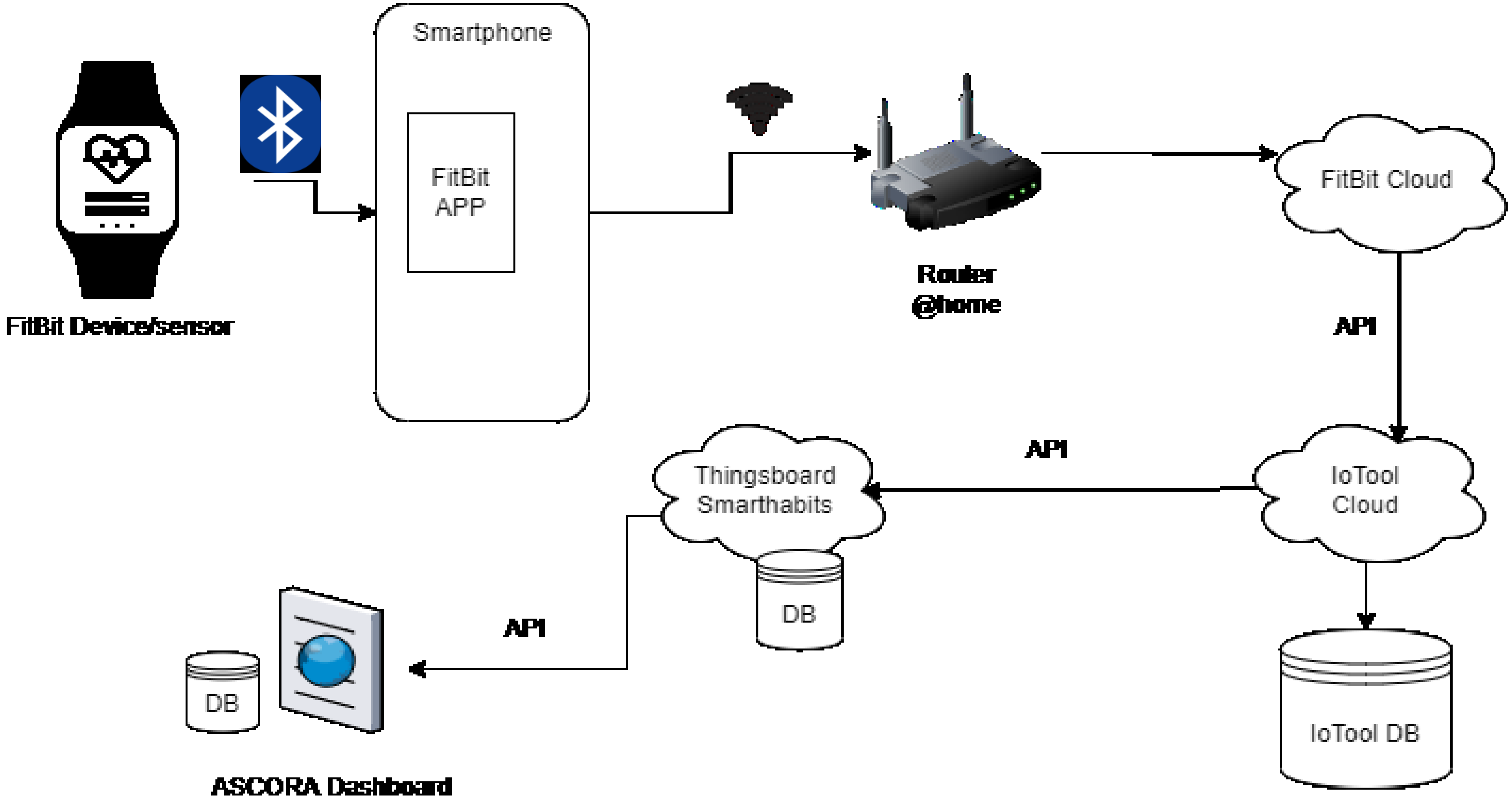
Variable/Measurement
Activity type (e.g. Walking)
Start time
Duration
Calories
Steps
Heart Rate
Sleep (Start time – End time)
Sleep phases (Start time – End time)

Even if there is no consensus on which is the best consumer device to track life-styles, there is sufficient evidence on the accuracy of FitBit and, when inaccurate, there is the evidence of the level of inaccuracy

The Data Flow with FitBit



Measures to minimize the impact on data protection

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- ✓ The smartphone delivered to the patient will be limited in its functions, as far this would be possible, so that it can only serve the purpose of data exchange between the device and the FitBit cloud
- ✓ No user personal data will be put in the smartphone
- ✓ When setting up the user profile in the FitBit application the pilot team will:
  - adopt a pseudonym that will not be intelligible enough so as to be linked to the identity of the person to whom the data refer
  - use ghost data for the parameters (name, surname, body and weight) that don't affect device measurements. The convention is to approximate body and weight to the closest higher multiple of 5 or 10.
- ✓ Considering all these elements in the production of the DPIA
- ✓ Collection of a granular consent from the final users


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YOU
MAAKE
JUSPAXAR
OBRIGADO
MATONDO
SALAMAT
KIITOS
KIA ORA
MULTUMESC
MOCHCHAKKERAM
TERMA KASIH
RAIBH MAITH AGAT
GRAZIE
MULTUMESC
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