

D2.7 – Protocols, standards, and manuals, including description of selected algorithms/sensor pairing in a format suitable to support regulatory approval [confidential]

Submitted: March 2022

Summary

The aim of WP2 is to produce a validated ‘single device location-algorithm pair’ to estimate digital mobility outcomes (DMOs) with data acquired from a wearable device located on the lower back. The provided solution will be used to extract clinically meaningful DMOs during the clinical validation study (CVS).

The aim of this deliverable is to present the work completed to ensure smooth adoption in the CVS of a given wearable device; including the developed algorithm to accurately estimate DMOs. This work included the following critical points:

1. Description of the protocol, the adopted standards and relevant manuals;
2. Description of the selected algorithm/device pair;
3. Summary of the performance of the selected algorithms and associated practical recommendations;
4. Evaluation of the algorithm performances when applied to a body attached device.

Leveraging on the experience gained during the technical validation study (TVS), WP2 has supported the design of the CVS protocol, the description of the adopted standards and the relevant manuals, which have been circulated among all the clinical centres. This deliverable reports on the technical support provided by WP2, in strict collaboration with WP3, to enable both the kick-off of the CVS data collection and its smooth progression.

Moreover, the essential characteristics of the algorithms that will be used identify walking periods (i.e., walking bouts, WB) and to extract different DMOs are also described, with the aim of supporting both WP5 and WP6 activities. The algorithms have been developed following a definition-driven pipeline (Figure 1-1), which entails different algorithmic steps adopted for the various pipeline’s steps (namely gait event detection, step length estimation, stride identification, WB identification). For each cohort, based on the results obtained for the validation performed on the data from the TVS, extensively reported in **deliverable 2.6 “Results of the technical validation on slow walkers and description of the experimental protocol for WP4”**, the best algorithm adopted in each step has been identified for each of the cohorts of interest. This allowed to identify optimal cohort-specific pipelines, and the set of algorithms adopted in each cohort-pipeline are here summarised.

Additionally, in light of the need to include a new device as part of the CVS, WP2 has established a protocol to assess the algorithms performances when run on data coming from devices embedding different electronics and requiring a different attachment modality (specifically, body worn vs body attached). This also allowed WP2 to provide evidence that the pipeline is device agnostic and to quantify differences in the estimation of a given DMO (e.g., walking speed) associated with the above aspects. The preliminary results of this analysis enabled the inclusion of the Axivity as part of the CVS. Final results, associated extra-experiments still ongoing and it will form part of the work performed by WP2 in the coming months.