

Innovative ICT architecture with modular integrated component for new study profile:

SPRINTT study ICT structure

Eng. Gianluca Zia, Caretek, Torino, Italy

Backgrounds

The dedicated ICT infrastructure for Sarcopenia & Physical frailty in Older People: Multi Component Treatment Strategies (SPRINTT) was developed and implemented to support the clinical trial data gathering and management, building on the initial call requirements by the Innovative Medicines Initiatives (IMI). *SPRINTT project started on July 2014 and is expected to enrol 1500 participants over 70 years old in 14 centres across 9 European Member States. Participants will adhere to a multicomponent intervention, centred on increased physical activity plus nutritional monitoring, and each individual will be followed-up over 2 years.*

Methods

Data collection: SPRINTT ICT infrastructure is based on an electronic case report form (e-CRF) for the collection of clinical data, a Nutrition Frontend, a DXA Frontend and a Participant's Home Kit that includes the wearable device. A Communication Hub could be deployed at each participant's home.

At the study site clinical and biological data are manually entered through the e-CRF, according to a paperless procedure. For DXA imaging files, the SPRINTT DXA Frontend application was specifically developed in order to avoid manual data entry. The SPRINTT DXA Frontend drives the electronic document workflow between different Investigators and roles.

For 3-days Dietary record, the Nutrition Frontend application was specifically developed in order to collect food intake.

The physical activity data from Actimetry device, are automatically collected through Web services. The system is ready with two different devices and all the data is collected without intervention of patients.

Data aggregation and the Enterprise Service Bus (ESB): in our ICT infrastructure the Clinical Knowledge Hub allows to aggregate heterogeneous data from different sources in a common database, where all data generated during the clinical trial can be retrieved. In order to meet data security, traceability and flexibility requirements a further infrastructural component has been used: the Enterprise Service Bus (ESB) that governs all communication between modules and enabling the following functions:

1. tracking who is sending data and which data are transferred
2. filtering data flow based on the user authorization profile
3. data encryption
4. governing data flow in a centralized way
5. decoupling modules to reduce each other's dependency

The ESB allows easy update of the ICT system design, thus avoiding rebuilding the existing application when adjustments are needed or if other data should be gathered.

Conclusion

Clinical trials like SPRINTT may benefit from this new ICT architecture and the integration of heterogeneous data source with specialized applications, each dedicated to a specific function. Home based communication is a first enabling step to engage more directly the elderly participant in similar programs.