Building Data Rich Clinical Trials

Rendicontazione

Informazioni relative al progetto

CCE_DART

ID dell'accordo di sovvenzione: 965397

Sito web del progetto

DOI
10.3030/965397

Data della firma CE
18 Gennaio 2021

Data di avvio
1 Febbraio 2021

Data di completamento
31 Dicembre 2025

Finanziato da
SOCIETAL CHALLENGES - Health, demographic change and well-being

Costo totale
Nessun dato

Contributo UE
€ 5 999 411,25

Coordinato da
FUNDACIO PRIVADA INSTITUT D'INVESTIGACIO ONCOLOGICA DE VALL-HEBRON (VHIO)
Spain

Periodic Reporting for period 2 - CCE_DART (Building Data Rich Clinical Trials)

Periodo di rendicontazione: 2022-08-01 al 2024-01-31

Sintesi del contesto e degli obiettivi generali del progetto

Successful drug approvals in Precision Oncology (PO) using basket studies have also uncovered new challenges. Research in small patient populations suffers from sustainability and logistical issues. Platform trials are flexible solutions to test different drugs in different populations but entail management issues that compromise flows and translational research, being detrimental to patient and researchers. New technological and methodological concepts must be implemented. To overcome these limitations, Cancer Core Europe (CCE) has developed the Basket of Basket (BoB)

trial to provide personalized treatment to a larger number of patients by incorporating a multi-tiered molecular profiling platform, flexible modules targeting different molecular alterations and a data/sample collection plan to enable translational research. The CCE_DART project, is conceived to address other limitations of PO and platform trials identified by our team. With a new design, we aim to improve efficiencies and transform platform trials in data-rich translational research programs by (1) developing digital systems facilitating the data management and clinical-decision-making; (2) integrating accurate, dynamic imaging and molecular markers of tumour progression/drug response; (3) using more efficient clinical trial methodology; (4) increasing patient engagement. To achieve this, we use technological/legal/clinical infrastructure developed in CCE and the BoB trial, that will be leveraged as a use case. The new concept will impact the design of new clinical trials consolidating a self-sustainable, data-rich, multi-endpoint global platform for clinical/translational research, encompassed by a pharmacoeconomic assessment that will proof the sustainability of the model for its implementation in the Health System as a return to society.

Lavoro eseguito dall'inizio del progetto fino alla fine del periodo coperto dalla relazione e principali risultati finora ottenuti

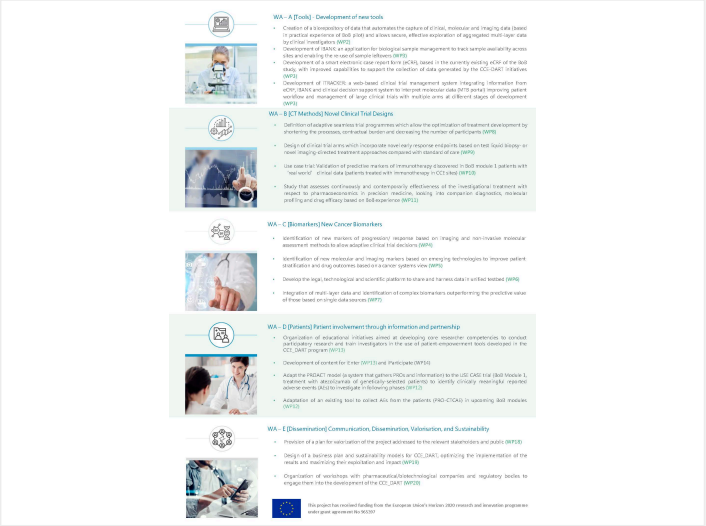
WA-A: Tools
We have developed biorepositories of data that automates the capture of clinical, molecular, and imaging data and allows secure, effective exploration of aggregated multi-layer data by clinical investigators. It incorporates a user-friendly tool for the navigation and analysis of the data to facilitate the clinical decision making (WP2). In addition, we have developed and implemented two different tools to facilitate the clinical trial management. iTRACKER, a web-based Clinical Management System to optimize study workflows; iBANK, a virtual biorepository of data; and the elevated eCRF a digital system that goes beyond conventional data recording, integrating all the developed tools in the project to facilitate the analysis of multi-parameter data for clinical decision-making (WP3).
WA-B: Methods
We have continued in silico modelling of both novel adaptive, seamless clinical trial methods in a retrospective fashion and of circulating biomarkers. (WP8 and WP9). In addition, we have the approvals in place in two sites to start the RELEVANCE study (a real-world data basket validation trial) and the rest are in the process of obtaining the approval (WP10).We have also finalized the health economic evaluation that assesses effectiveness of the investigational treatment alongside the BoB trial as a use case. An online course summarizing the learnings and implications of the health economics activities, with a focus on estimating cost-effectiveness and budget impact using clinical data from innovative trials, is published on the project website (WP11).
WA-C: Biomarkers
We have established the repositories to manage the project data. Molecular data undergoes format harmonization and annotation via a local instance of the MTBP. We have also developed specifications on sample processing and shipping as well as the technical specifications for data processing and analysis for plasma proteomics and ctDNA (WP4). On the other hand, imaging biomarker validation utilizes a distributed image repository tool based on the JIP. Enhancements to the platform, specifically tailored for CCE_DART, include additional documentation sections to support the development of analytical methods and local platform operation (WP6). Real-world data

and open-access datasets have been used for temporary training. We have validated the setup, showing potential for distributed deep learning tool development (WP4 and WP5). Moreover, progress has been made in refining AI-based methods for biomarker discovery in multi-omics data. Methods include explainable ML for complex gene interaction patterns and a transformer-based model for leveraging multi-centre datasets. A pipeline for enriching molecular signatures with external evidence has also been developed. Core technical contributions are completed, with validation and publication preparation ongoing (WP7).
WA-D: Patient
The sub-study to collect Patient Reported Outcomes (PRO) in clinical trials using the PROACT 2.0 tool is ready to start, and it operates independently from the BoB trial for broader patient recruitment (WP12). As for WP13, we have executed two workshops for researchers to promote patient participation in research activities (Participatory Research). In addition, we have developed and launched iENTER, a website mainly aimed at improving the informative process for patients who are potentially eligible to the BoB trial. Two other tools integrated with iENTER were developed within WP14: iCONSENT (web app to enhance the Informed Consent Process of patients going to decide about participating in the BoB trial; delivered during RP1 and iPARTICIPATE (web app with personalized access to BoB trial information and to communication tools for enrolled patients; delivered during RP2). Piloting of these WP13 and WP14 web tools will be performed during the next RP in the exploitation WP19.
WA-E: Dissemination
Dissemination activities have been carried out in accordance with the project communication plan (WP18). We have also defined and exploitation strategy for the project. Two KERs (iTRACKER and iENTER) have been analysed and one of them, iTRACKER, is on Business plan preparation. In addition, maintenance and the piloting of some studies is going on (WP19). Finally, we are organizing the second workshop with key stakeholders to develop a consensus around the application of new clinical trial methods in clinical drug development.

Progressi oltre lo stato dell’arte e potenziale impatto previsto (incluso l’impatto socioeconomico e le implicazioni sociali più ampie del progetto fino ad ora)

In the previous section, we have described all the tasks beyond the state of the art that have been carried out. CCE_DART project improves the design of clinical trials in the field of Oncology, as it addresses and amends the most important challenges of current designs. The model will allow to significantly save time and costs, improving the design, quality, efficiency, and analysis of clinical trials, specifically IITs. We aim to reshape the clinical trial’s concept which would ultimately increase the EU's leadership in cutting-edge clinical research with ultimate benefit for cancer patients; and accelerate the technological progress and competitiveness in the development of new tools associated with clinical research.
Several publications have been released in open access and public deliverables uploaded to the project website, all aiming to incorporate newer and more effective methods into the design, conduct, and analysis of academic clinical trials. In addition, other project results are already available for the

wider society, such as an online course summarizing the learnings and implications of health economics activities and a keynote session on AI.



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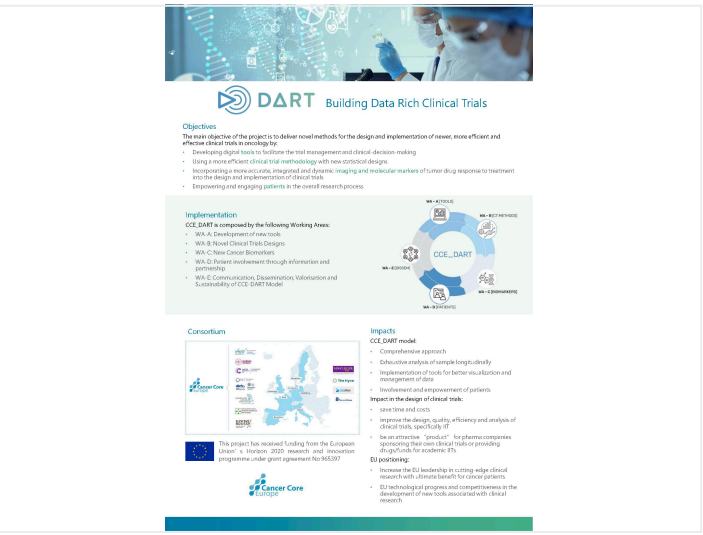

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Ultimo aggiornamento: 9 Luglio 2024

Permalink: https://cordis.europa.eu/project/id/965397/reporting/it