An electronic registry for Older Adults Long-Term Health Trajectories during Covid-19 pandemic: the Gerocovid and Gerovax approach.

Susanna Del Signore ^{(1) (2)}, Raffaele Antonelli Incalzi ⁽³⁾, Graziano Onder ⁽⁴⁾, Alba Malara ⁽⁵⁾, Caterina Trevisan ^{(6) (12)}, Angela Marie Abbatecola ⁽⁷⁾, Gianluca Zia ⁽²⁾, Stefania Del Signore ⁽²⁾, Annapina Palmieri ⁽⁴⁾, Anna Di Lonardo ⁽⁴⁾, Gilda Borselli ⁽⁸⁾, Marcello Russo ⁽⁷⁾, Marianna Noale (9), Stefano Fumagalli ⁽¹⁰⁾, Pietro Gareri ⁽¹¹⁾, Enrico Mossello ⁽¹⁰⁾, Stefano Volpato ⁽¹²⁾, Fabio Monzani ⁽¹³⁾, Alessandra Coin ⁽⁶⁾, Giuseppe Bellelli ⁽¹⁴⁾, Chukwuma Okoye ⁽¹³⁾, Elisa Bottoni ⁽¹⁵⁾, Carmine Cafariello ⁽¹⁶⁾ on behalf of the GeroCovid Observational & GeroCovid Vax Group

1) Bluecompanion France, Jambville, France	2) Bluecompanion ltd, London, United Kingdom	3) Unit of Geriatrics, Department of Medicine, Campus Bio- Medico University and Teaching Hospital, Rome, Italy	4) Department of Cardiovascular, Endocrine-Metabolic Diseases and Aging, Istituto Superiore di Sanità, Roma, Italy
5) ANASTE-Humanitas Foundation, Rome, Italy	6) Geriatrics Division, Department of Medicine (DIMED), University of Padua, Italy	7) Azienda Sanitaria Locale (ASL) Alzheimer's Disease Day Clinic, Frosinone, Italy	8) Italian Society of Gerontology and Geriatrics (SIGG), Florence, Italy
9) Aging Branch, Neuroscience Institute, National Research Council, Padua, Italy	10)Geriatric Intensive Care Unit, Department of experimental and Clinical Medicine, University of Florence, Italy	11)Center for Cognitive Disorders and Dementia – Catanzaro Lido, ASP Catanzaro, Italy	12) Department of Medical Science, University of Ferrara, Italy
13)Geriatrics Unit, Department of Clinical and Experimental Medicine, University of Pisa, Italy	14)School of Medicine and Surgery, University of Milano-Bicocca and Acute Geriatric Unit, San Gerardo Hospital, Monza, Italy	15)Centro Benessere (Rehabilitation center) Frosinone, Italy	16)Geriatrics Outpatient Clinic and Territorial Residences, Italian Hospital Group, Rome, Italy







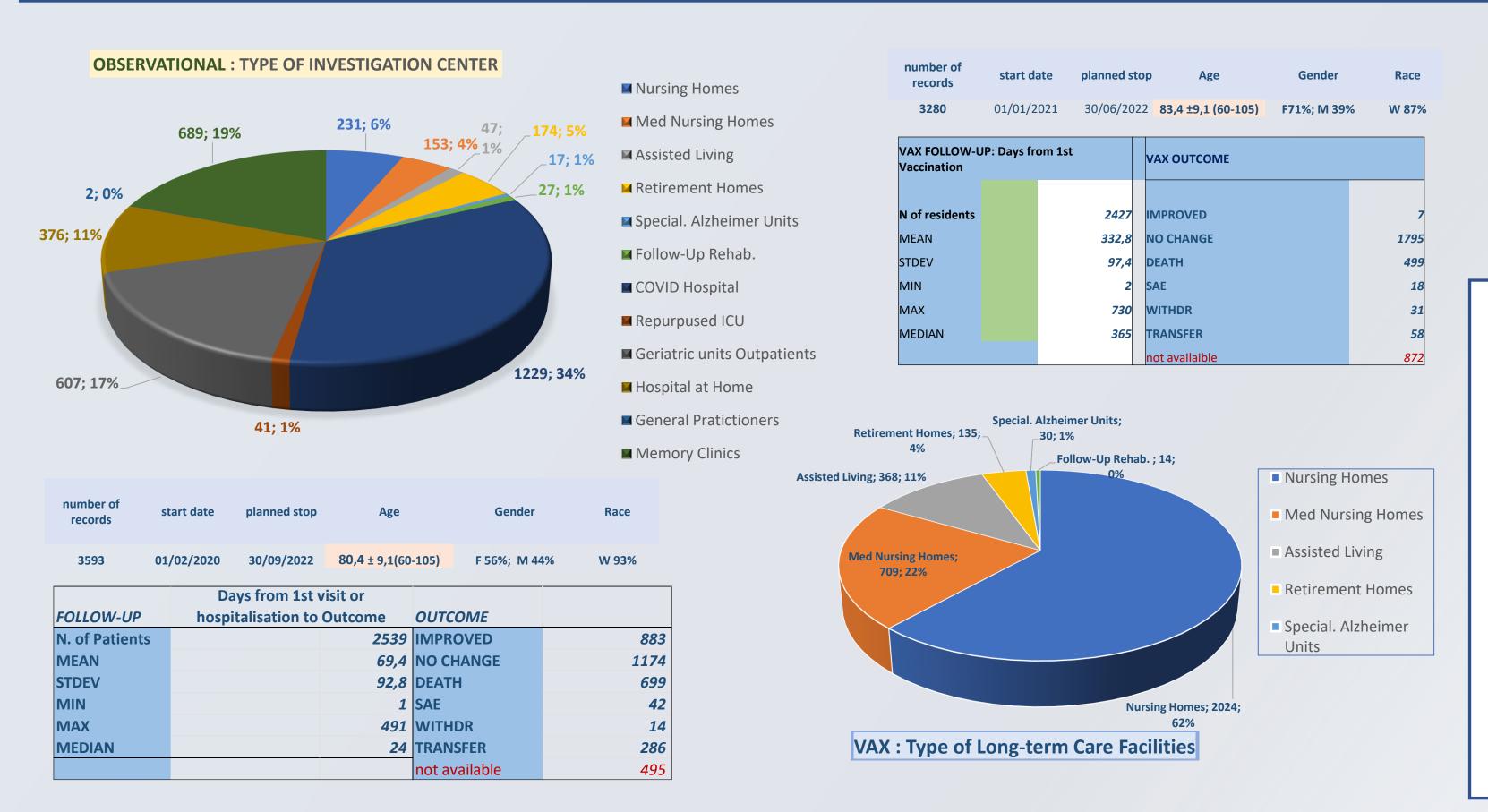


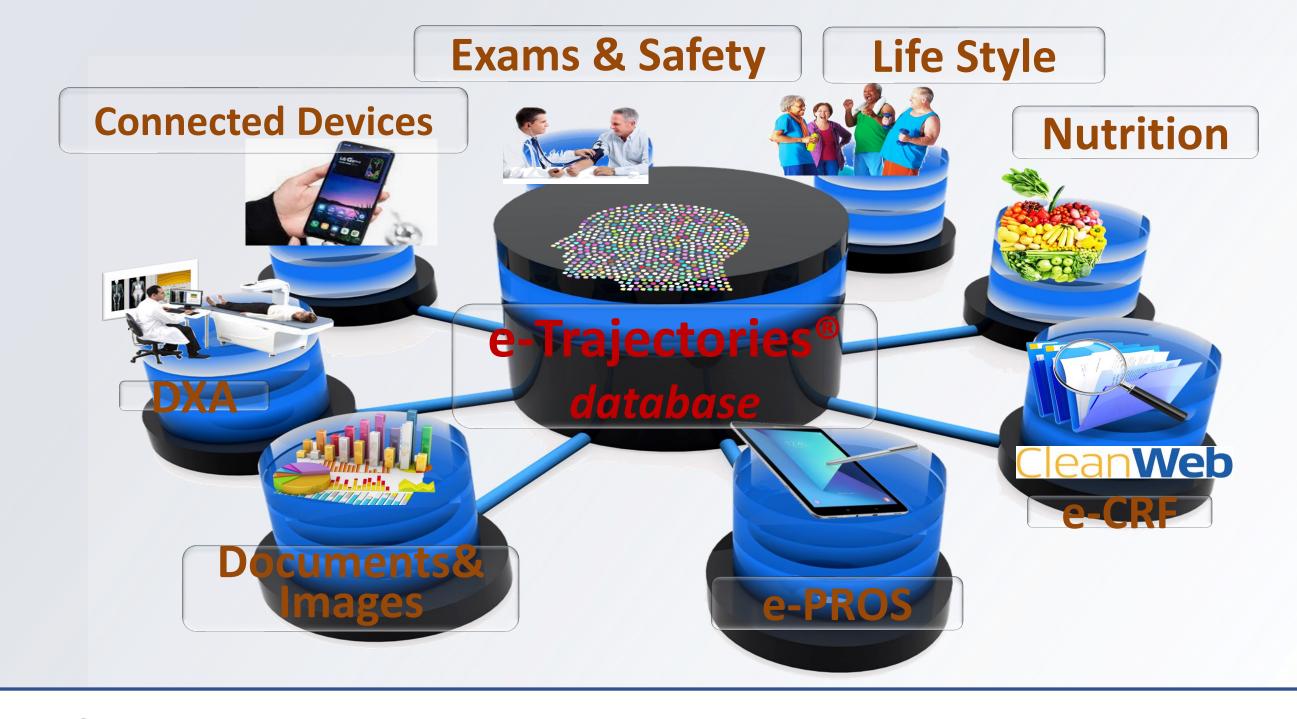


Introduction On March 2020, Bluecompanion developed a web-based electronic registry in partnership with the Italian Society of Gerontology and Geriatrics (SIGG), to capture long-term clinical trajectories of older persons suffering or at-risk of COVID-19 across geriatrics practices and residential facilities. "Gerocovid Observational" followed 3593 participants in 86 Italian and 3 Norwegian investigational sites.

Objective To adapt Gerocovid e-registry, a multidisciplinary geriatric investigational tool, to the different phases of Covid-19 pandemic.

Methods Bluecompanion's e-Trajectories, is based on a CleanWeb engine (Telemedicine-Technologies, France). Servers are located in the EU, and operations compliant with the European General Data Protection Regulation (GDPR), ISO 9001 certification and FDA CFR 21 part 11. Bluecompanion provided on-line training sessions for investigators, as well as technical support. Data collection underwent quality checks and investigators were required solve raised queries. All individual clinical data were anonymized before data entry.





Results

In March 2021 the e-registry was adapted as the eCRF of Gerovax, an Italian Medicines Agency (AIFA) sponsored observational clinical trial led by the Istituto Superiore di Sanità (ISS).

"GeroVax" enrolled 3280 vaccinated residents in 73 Italian Long Term Care Facilities, observed for 12 months after the first dose vaccination. Data collection covered the lapse from December 2020 to June 2022.

The standardized clinical data capture allowed to test several statistical hypotheses to clarify the influence of initial clinical characteristics over the short and long-term health and vaccination outcomes.

Conclusions

Overall, the development of a specialised web-based investigational data platform generated a conspicuous amount of high-quality longitudinal clinical data despite a critical context, the COVID-19 pandemic, and succeeded to study an often "difficult to reach" population, older persons suffering from multiple comorbidities, living in the community or in Nursing Homes.

E-Trajctories, a geriatric multidisciplinary web-based e-registry enabled high-quality longitudinal clinical data follow-up in approximately 6000 older persons suffering from multiple comorbidities, living in the community or in LTCF, and to analyse **complex health trajectories after COVID-19 vaccination**.

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