

European DO-HEALTH Clinical Trial Aims at Simple, Affordable Interventions to Improve Senior Health



Creating a Biobank for Evaluation of Future Biomarkers

By Francois Hamy, PhD, Director, Fisher BioServices, Basel, Switzerland

With special thanks to Asa Muller, PhD, Heike A. Bischoff-Ferrari, MD, PhD, and the DO-HEALTH Coordinating Team





Biobanking & Biorepository



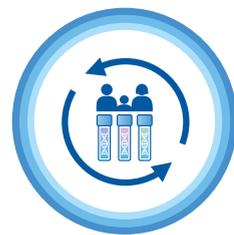
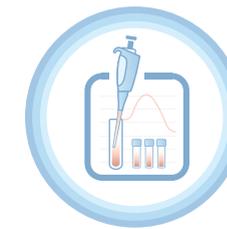
Cell Therapy Solutions



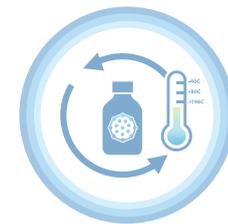
Clinical Trial Kit Production



Laboratory Processing



Clinical Trial Sample Management



Biologic-API Management



Qualification / Validation Services



Cold-Chain Logistics

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About the Author



Dr. François Hamy manages Fisher BioServices' operations in Basel, Switzerland. In this role, he is responsible for processing and analyzing samples as well as managing the Biomarker Laboratory, which uses extensive genomics, proteomics, phenomics, and metabolomics studies to support clients' needs in biomarker development. Dr. Hamy is also a major contributor to the technical innovation team at Fisher BioServices, which focuses on supporting customers' project needs and challenges. This often includes designing and developing custom solutions for biobanking, clinical trial materials management, and ultra-cold chain logistics.

Dr. Hamy served for 11 years as a research group leader in virology/oncology in the pharmaceutical industry and also has six years of experience in leading a virology/oncology diagnostic company. He received his PhD training in molecular biology at the University of Lille, France, and completed his Masters Degree in Pharmacology and Drug Design from the University of Nottingham, U.K.



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1 Introduction



Introduction

As the European population rapidly ages, the growing number of seniors with age-related chronic diseases presents a challenge to European societies and health care systems. Therapeutic interventions that are effective, affordable and well-tolerated in the prevention of chronic disease could have an outstanding impact on public health as a whole and are urgently needed. Among the most promising interventions that meet these requirements are vitamin D, marine omega-3 fatty acids and physical exercise. However, their individual and combined effects have yet to be confirmed in a clinical trial.

DO-HEALTH is Europe's largest clinical trial in support of health at an older age, and the name is derived from the interventions under study: the Vitamin **D3-Omega3-Home Exercise - HeALTHy** Ageing and Longevity Trial. A large, three-year, multi-centre clinical trial, the DO-HEALTH study will generate needed efficacy and safety data for the three interventions in the prevention of age-related diseases in seniors.





Introduction

**Primary
Endpoints**



**Secondary
Endpoints**

The primary endpoints are bone health (the incidence of non-vertebral fractures), muscle strength (measured through functional decline), cardiovascular health (changes in systolic and diastolic blood pressure), brain function (cognitive decline), and immune system health (rate of infection). Researchers will also be looking at secondary endpoints, including risk of hip fracture, rate of falls, pain in symptomatic knee osteoarthritis, dental /oral health, gastro-intestinal symptoms, mental health, quality of life, and life expectancy. Exploratory endpoints, such as incidence of major cardiovascular events and functional recovery after bone fracture, are also planned.

DO-HEALTH will further assess the comparative effectiveness of the interventions by evaluating reasons why or why not seniors comply with the regimens, and will assess their cost-benefit in a health economic model based on documented health care utilization and observed incidence of chronic disease.

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2 The DO-HEALTH Participants



The DO-HEALTH Participants

The DO-HEALTH trial will enroll 2,152 community-dwelling men and women aged 70 and older, at the time of life when the rate of chronic diseases in the population increases substantially. The randomized-controlled trial will test the individual as well as the combined benefits of 2000 IU of vitamin D/day, 1.0g of omega-3 fatty acids/day and a simple home exercise program in an efficient factorial trial design.

The volunteers will be randomized into a 2x2x2 factorial design involving the three interventions as illustrated on the left.

The DO-HEALTH seniors are being recruited from seven European sites (Zurich University Hospital, Switzerland; Basel University Hospital, Switzerland; University of Geneva, Switzerland; Toulouse University Hospital, France; Charité Clinic, Berlin, Germany; Innsbruck Medical University, Austria; and Coimbra University, Portugal). Recruitment began in December 2012 and reached 50 percent of the target by December 17, 2013.

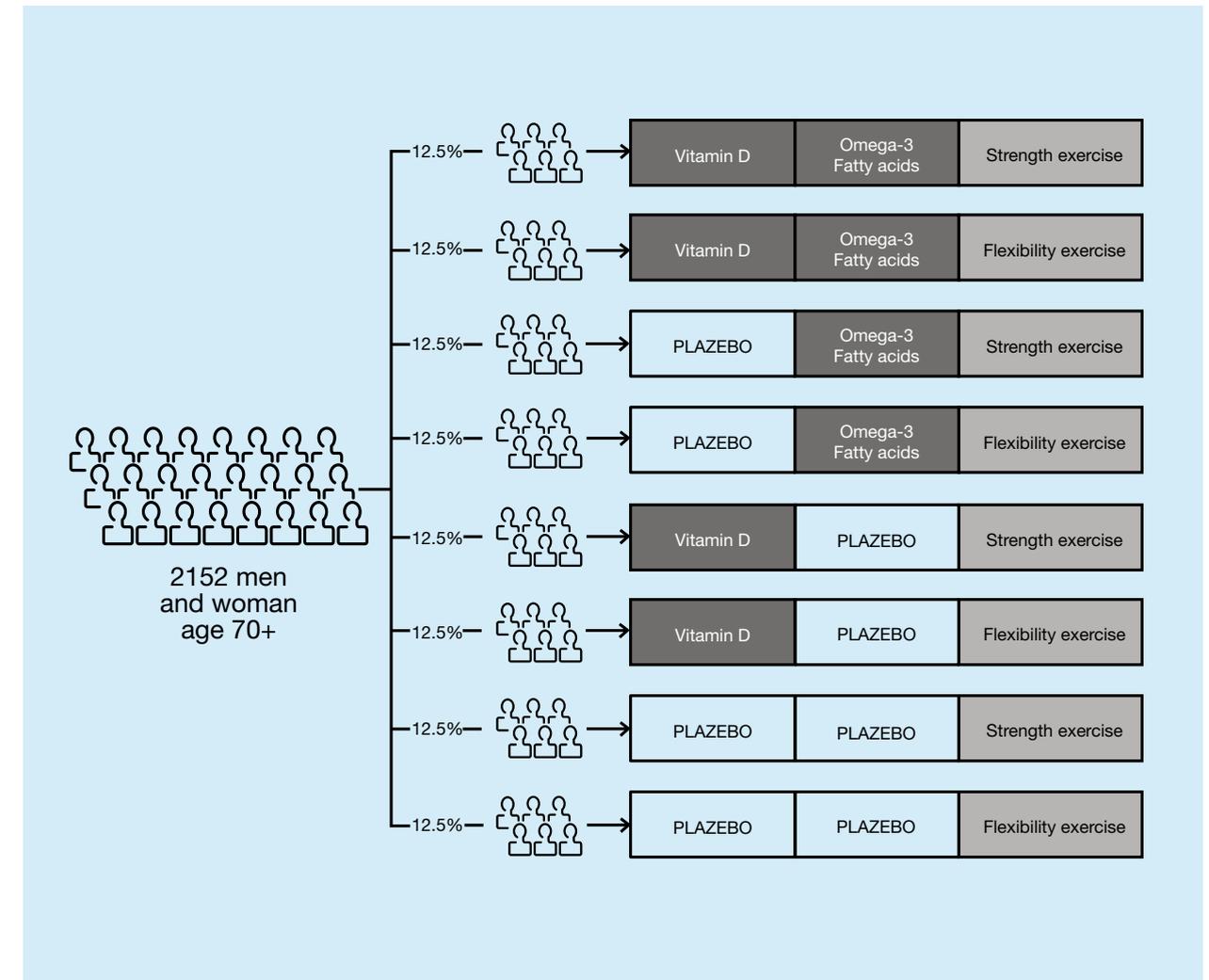


Diagram courtesy of the DO-HEALTH Coordinating Team

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③ Endpoints



Endpoints

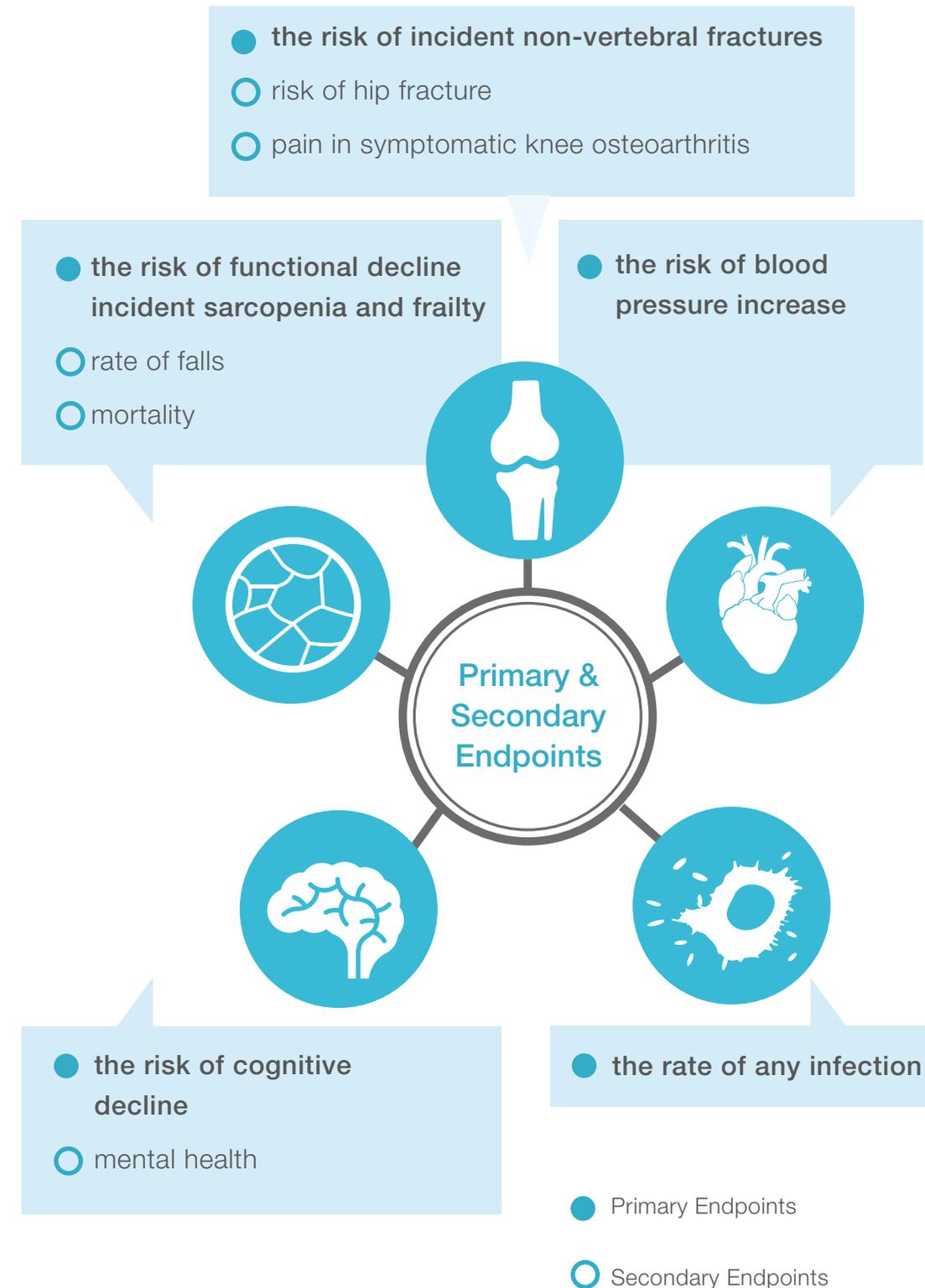
An overarching goal of the DO-HEALTH clinical trial is to prolong healthy life expectancy at older age and to reduce healthcare costs by implementing effective and broadly applicable disease prevention interventions.

DO-HEALTH will establish evidence in five primary endpoints:

- the risk of incident non-vertebral fractures,
- the risk of functional decline,
- the risk of blood pressure increase,
- the risk of cognitive decline, and
- the rate of any infection.

Key secondary endpoints include:

- risk of hip fracture,
- rate of falls,
- pain in symptomatic knee osteoarthritis,
- incident sarcopenia and frailty
- mental health,
- quality of life, and
- mortality.



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4 A Biobank for Biomarkers



A Biobank for Biomarkers

The DO-HEALTH clinical trial is also creating a biobank of processed DO-HEALTH samples for downstream research, greatly enhancing the potential value of the data collected during the interventions and potentially enabling the development of other preventive strategies. Blood and urine samples are being collected from the participants to measure the effect of the interventions at the cellular level via a large number of biomarkers.

The University of Zurich, in its role as the coordinating site, chose Fisher BioServices to provide biobanking services for the DO-HEALTH Trial. Fisher BioServices has a global footprint and a location at Basel, close to the coordinating site at the University of Zurich. In addition, as an organization devoted to specimen management and biorepository storage, the company can ensure that the samples would be stored in validated freezers with temperature monitoring, that after-hours technicians were always available to respond to mechanical issues, the samples would be handled according to best practices, and that all risk mitigation infrastructure was in place, at an advantageous cost.



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A Biobank for Biomarkers



The samples are collected and aliquoted at the clinical sites and then frozen. At quarterly intervals, the seven sites ship the patient biospecimen to the DO-HEALTH biobank at Fisher BioServices. When the biospecimen arrive at Fisher BioServices, the vials are further divided into subsets. The first subset includes the aliquots that will soon (within a year and a half) be sent to one of four laboratories for analysis of biomarkers. The second subset will be retained for up to 30 years for downstream research. When the biomarker analyses begin, Fisher BioServices will retrieve the first subset of samples from storage and send them to the designated laboratories.

Coordinated by the University of Zurich (Centre on Aging and Mobility), analysis of large set of biomarkers will be performed to both monitor endpoints of the interventions and also to fill knowledge gaps in the clinical care of seniors. For instance, most reference values for these biomarkers are derived from middle-aged adults; data on biomarker norms for those over age 65 are missing. The biomarkers to be quantified will address the entire spectrum of health, and the data gained will support health at older age by helping to establish norms in this population.



5 The DO-HEALTH Team



The DO-HEALTH Team

DO-HEALTH is primarily funded by the European Commission Seventh Framework Programme (EC Framework 7), and is led by Professor Heike A. Bischoff-Ferrari, MD, PhD, Director, Centre on Aging and Mobility, Zurich University Hospital and City Hospital Waid, Zurich, Switzerland. Prof. Bischoff-Ferrari is the DO-HEALTH principal investigator and coordinator, as well as the director of the recruitment center at the Universität Zürich.

The EC Framework 7 provided a 6-million Euro grant, supplemented by the participating Universities and three industrial sponsors (DSM Nutritional Products, Roche and Nestlé Health Science) who help bring the total DO-HEALTH budget to 12.8 million Euros.

The DO-HEALTH website (<http://do-health.eu/wordpress>) provides a continuous update on recruitment. Information is also available at the study's EC website: http://ec.europa.eu/research/health/medical-research/human-development-and-ageing/projects/do-health_en.html. Additional information about EC Framework7 can be found at <http://ec.europa.eu/researchg/fp7>.





Additional Resources

As a worldwide provider of biobanking and clinical trial sample management, Fisher BioServices can assist companies looking to store critical biological materials, biotherapeutics, manufacture sample collection kits, and process samples.

- Simple to complex sample collection kit design and production
- Sample processing, global biobanking, and data management
- Online access to inventory for data searching, requesting samples, and exporting reports

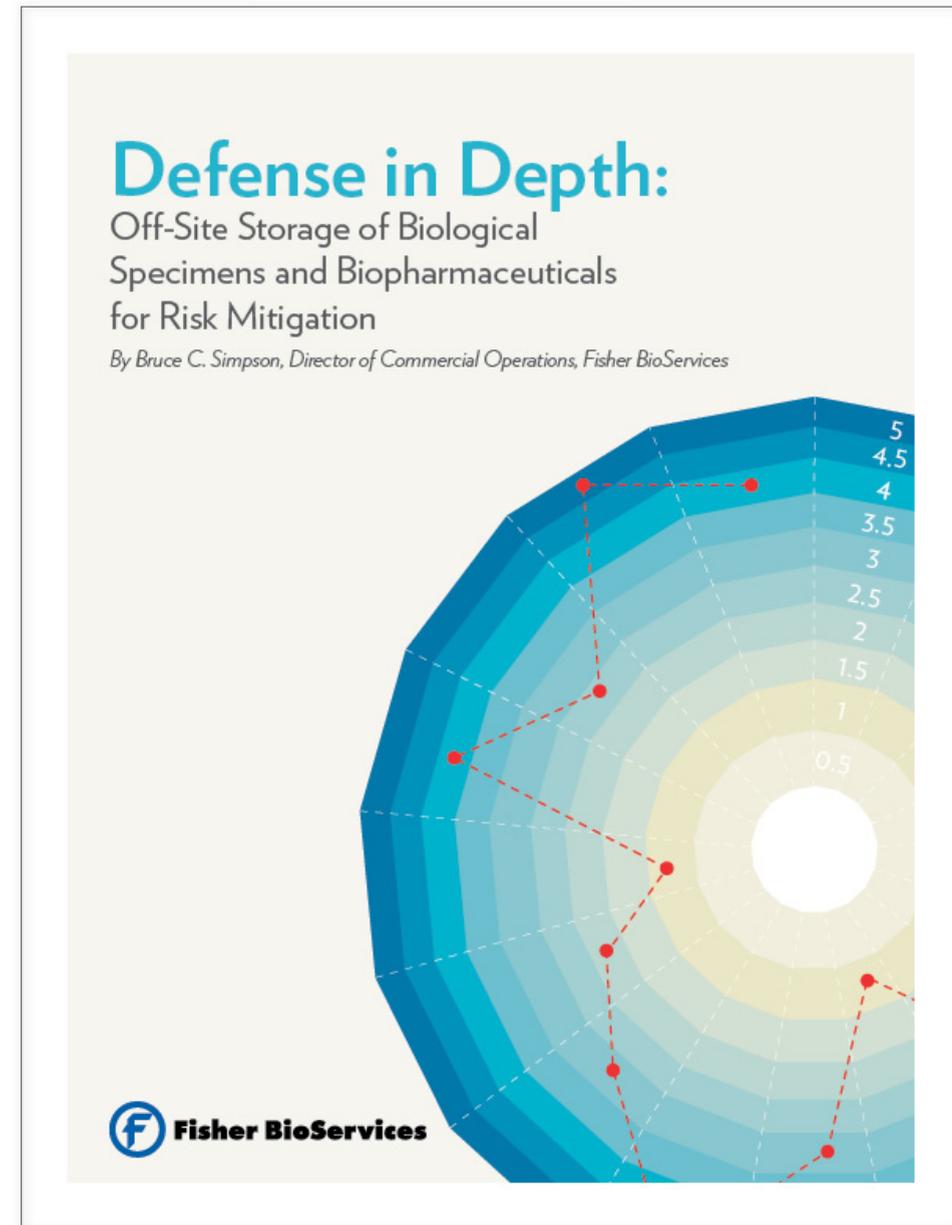
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