



HUMAN TISSUE AND BIOFLUIDS PROCUREMENT

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FIDELIS RESEARCH recognizes the increasing importance of biospecimens, which are becoming essential tools for the translation of our client's research into new products.

FIDELIS RESEARCH has supply agreements with a broad network of sites in the South East Europe region, allowing us to provide our customers with both commonly used and difficult to find human tissue and biofluid specimens for translational research.

FIDELIS RESEARCH collaborates with KOLs

from its collection sites where donors are identified, consent is obtained, and specimens are collected.

FIDELIS RESEARCH has built a reputation of a professional partner providing hard to find human tissue specimens and biofluids. The quality of the specimens and the methods we use for their collection assure that researchers have access to high volume of research specimens with consistent information, quality and de-identified patient information.

FIDELIS RESEARCH's clients use the specimens we provide for:

- identifying the causes and mechanism of action of diseases
- identification of disease-relevant genes or mutations
- development of new drug molecules
- biomarker discovery in drug development

Before initiating your project, we will perform a feasibility study. Tailored feasibility studies help our customers better forecast their procurement plans and research and development timelines.



Each client defines project-specific parameters:

STUDY OBJECTIVES

- Purpose and scope
- Ethical standards, IRB/IEC and ICF approval elements for genomic research

PROJECT SPECIFICATIONS

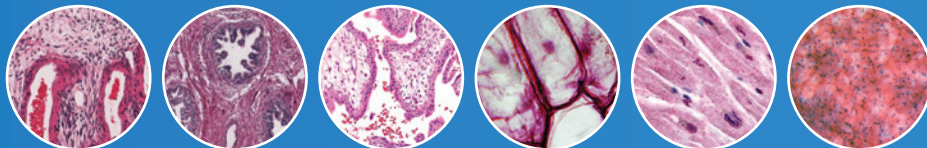
- Patient population: inclusion/exclusion criteria
- Specimens collection, preparation, labeling
- Laboratory processing (protocols, media)
- Specimens storage and shipment conditions

CLINICAL DATA

- Standard (medical history, physical examination, lab data)
- Project-specific CRF components
- Database use

LOGISTICS, DELIVERABLES AND TIMELINES





FIDELIS RESEARCH has successfully managed projects for collection of the following biospecimens:

- solid tumors
- hematological malignancies (AML, CML, MDS, B-cell Lymphoma, others)
- biological fluids (saliva, synovial fluid, ascites and others)

- inflammatory diseases
- metabolic disorders
- normal tissues
- Infectious diseases
- autoimmune disorders



FIDELIS RESEARCH can organize the storage and shipment of your specimens in the following temperature conditions:

- Fresh
- Frozen (Dry Ice; LN₂)
- FFPE blocks

www.fidelis-research.com

FIDELIS RESEARCH currently delivers specimens from consented patients to:

- North America
- Europe
- Asia

FIDELIS RESEARCH delivers to clients ethically procured specimens, therefore we always stay on top of all applicable regulations, such as:

- Specific country legislation
- EU Directives
- FDA CFRs
- HIPAA



FIDELIS RESEARCH

**FIDELIS RESEARCH implemented
ISO 9001:2008
Quality Management System in 2014**



Management
System
ISO 9001:2008

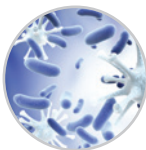
ABOUT US

FIDELIS RESEARCH is a Human Tissue Procurement company operating in South East Europe – Bulgaria, Romania, Serbia, Croatia, Turkey. The company's management and staff have decades of experience in medical research from early discovery through pivotal clinical trials.

FIDELIS RESEARCH manages projects involving human tissue procurement and clinical trials conduct.

FIDELIS RESEARCH has built reputation of a trustworthy and professional partner providing flexible, high-quality and focus services.

FIDELIS RESEARCH's clients include global pharmaceutical and biotechnology companies and research institutions in a broad range of therapeutic areas, as well as the NIH and NCI.



MISSION

Our mission is to deliver "Semper constans et fidelis" services to the pharmaceutical and biotechnology business by:

- Understanding client needs
- Communicating openly and in a timely manner
- Maintaining contemporary knowledge
- Being always flexible and oriented to client goals
- Improving the outcome for patients

VISION

FIDELIS RESEARCH's vision is that by providing high-quality services, in compliance with all applicable guidelines and regulatory requirements, we help our clients speed up R&D timelines, minimize odds of product failure and ultimately bring new treatment for every patient in need.

BULGARIA | CROATIA | ROMANIA | SERBIA | TURKEY

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