



# The Companies of Experts

**Our Organisation**

**Our Approach**

**Your Benefit**



## The Companies of Experts

- **Medical Research**
  - **Marketing Access**
  - **Medical Management**
- in Europe & Saudi Arabia**

**by**

**LaNova & INNOVA**



## Introduction

LaNova is a CRO / SRO as well as a Medical Management Organisation for the international life science industry working in Europe and for the Middle East Region.

Our clients are Pharmaceutical / Biotech Companies but also Startups and Institutional Research / Medical Centers and Private Companies who want to extend to Centers of Excellence.

## **LaNova for Europe & KSA:**

1. **CRO** — Clinical Research Organisation → clinical trials
2. **SRO** — Scientific Research Organisation → scientific projects
3. **MMO** — Medical Management Organisation → consulting of Medical Management
4. **Scientific Research Trainings**  
(GCP/ICH & GPP, Regulatory Affairs, Pharmacovigilance)



## **INNOVA CTMD**

is the 1. CRO in KSA  
approved  
by the sFDA

as Joint Venture Company  
between

**LaNova Consulting s.r.o.**

and

**INNOVA HC LLC**



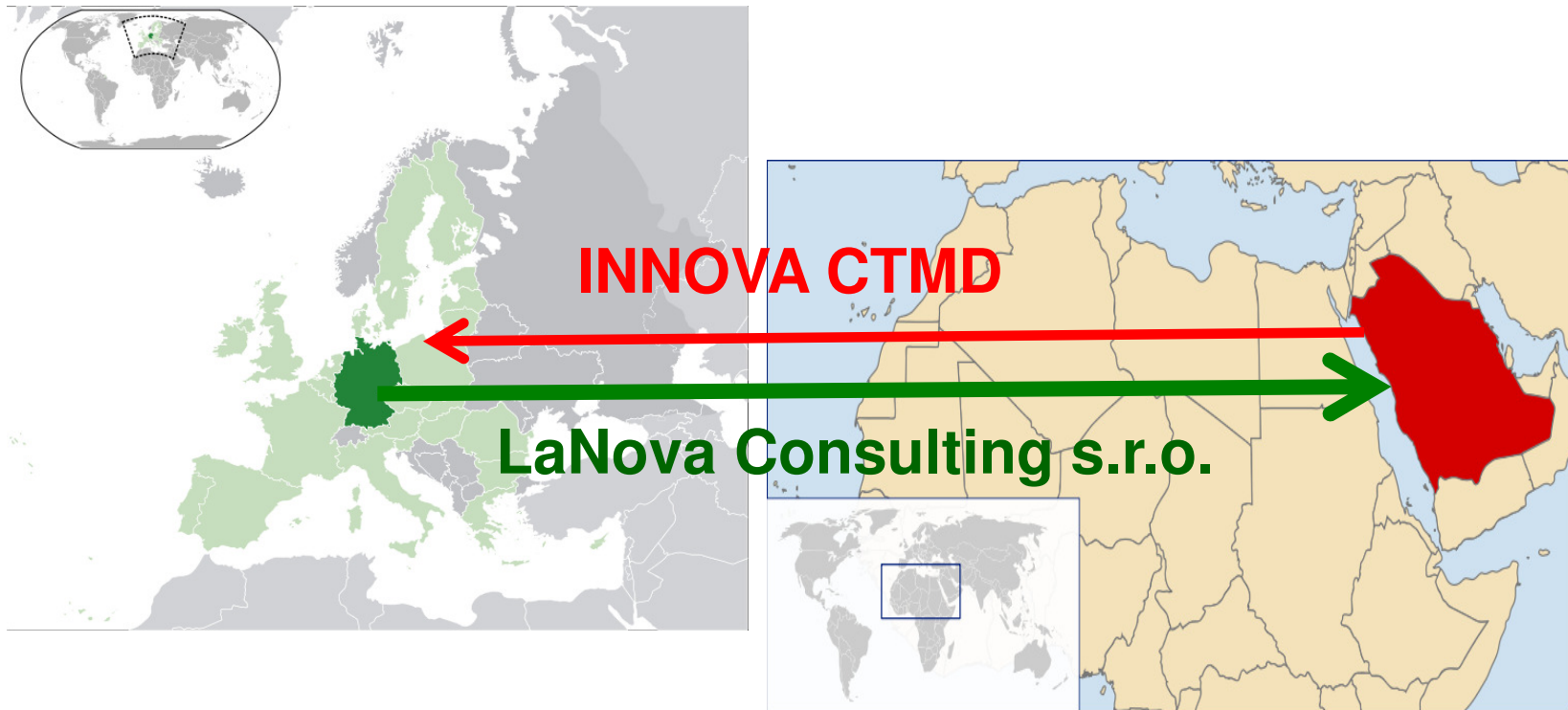
## **INNOVA CTMD LLC**

### **INNOVA Clinical Trail Monitoring & Development**

#### **Tasks: CRO & SMO**

- **Planning, Conducting and Analysing of Clinical Studies**
- **Access to all Hospitals focusing on Medical Research in in KSA → CRAFT**
- **Direct Link to SaudiFDA**
- **Direct Link to Health Care & Medical Research companies and BioTech in KSA**
- **Management of Scientific Research Proposals forwarded to KACST**
- **Interface to European HealthCare & Pharmaceutical Industry → LaNova**

# Transfer of Knowledge in Medical Research by LaNova & INNOVA



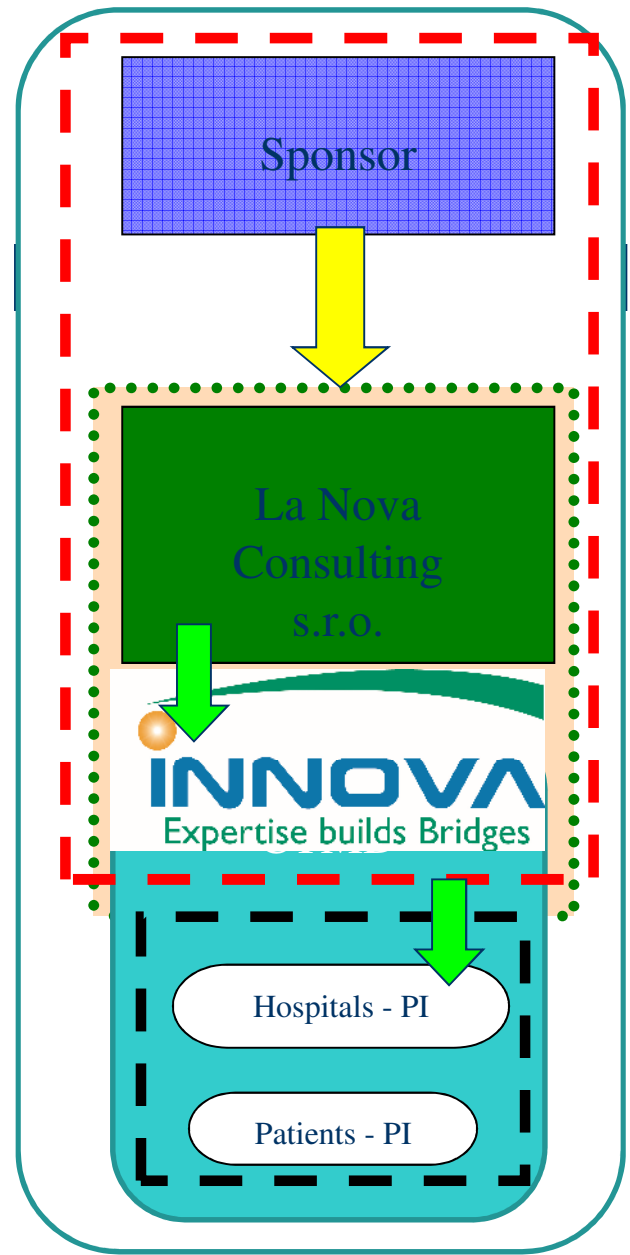
# Overview by Contract Management



Research Co-operation

LaNova & INNOVA

Investigator Contract 1  
CRO → PI  
or  
Sponsor → PI



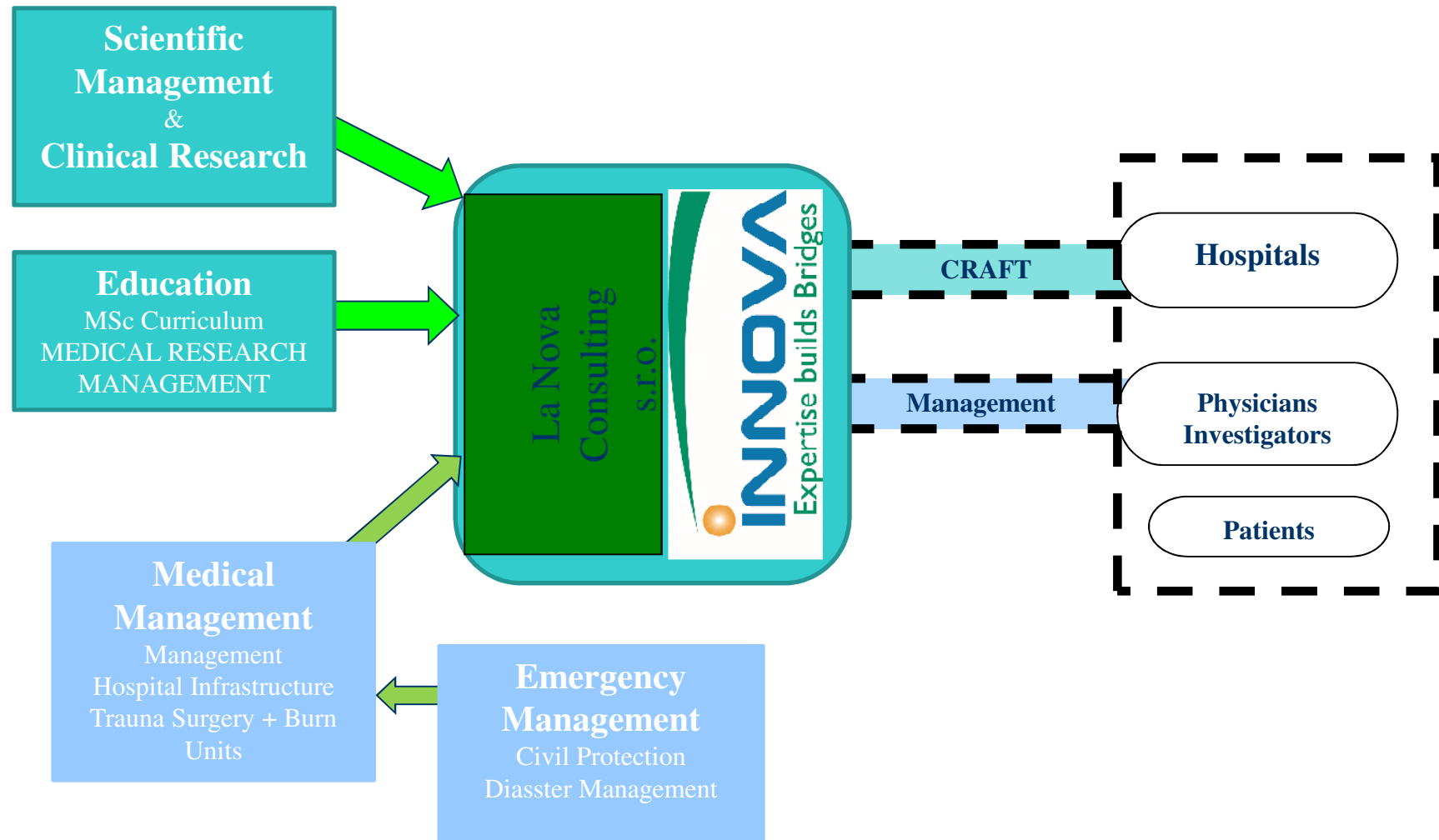
Research Contract

Individual Project Contract

Employment Contract



## Overview by Capabilities





# Overview

# LaNova Consulting s.r.o.

## CSO and Co-founder

- Study of Medicine and Law
- 16 years experience in R&D and business development
- Qualified Person for Pharmacovigilance (EMA)
- Commissioner of the Graduated Plan / Germany (2000-2002)
- Independent Expert / Consultant for Medical Science - European Commission (FP 6 – FP 7)
- EFQM Assessor
- Lecturer University Hannover
- ICR Representative for Germany
- Member of the UniMed Verlag Advisory Board
- Different board memberships

## Strong background in

- Clinical Research Development
- Medical affairs
- Pharmacovigilance
- Medical Writing
- Scientific Medical Review
- Project Management
- Outsourcing Management
- Corporate Development
- Business Development
- Medical Management – HELIOS Kliniken
- Medical Education
- Rescue Management – KatS Hessen

# Living Co-operations



Arabio



BIOCLINICA™



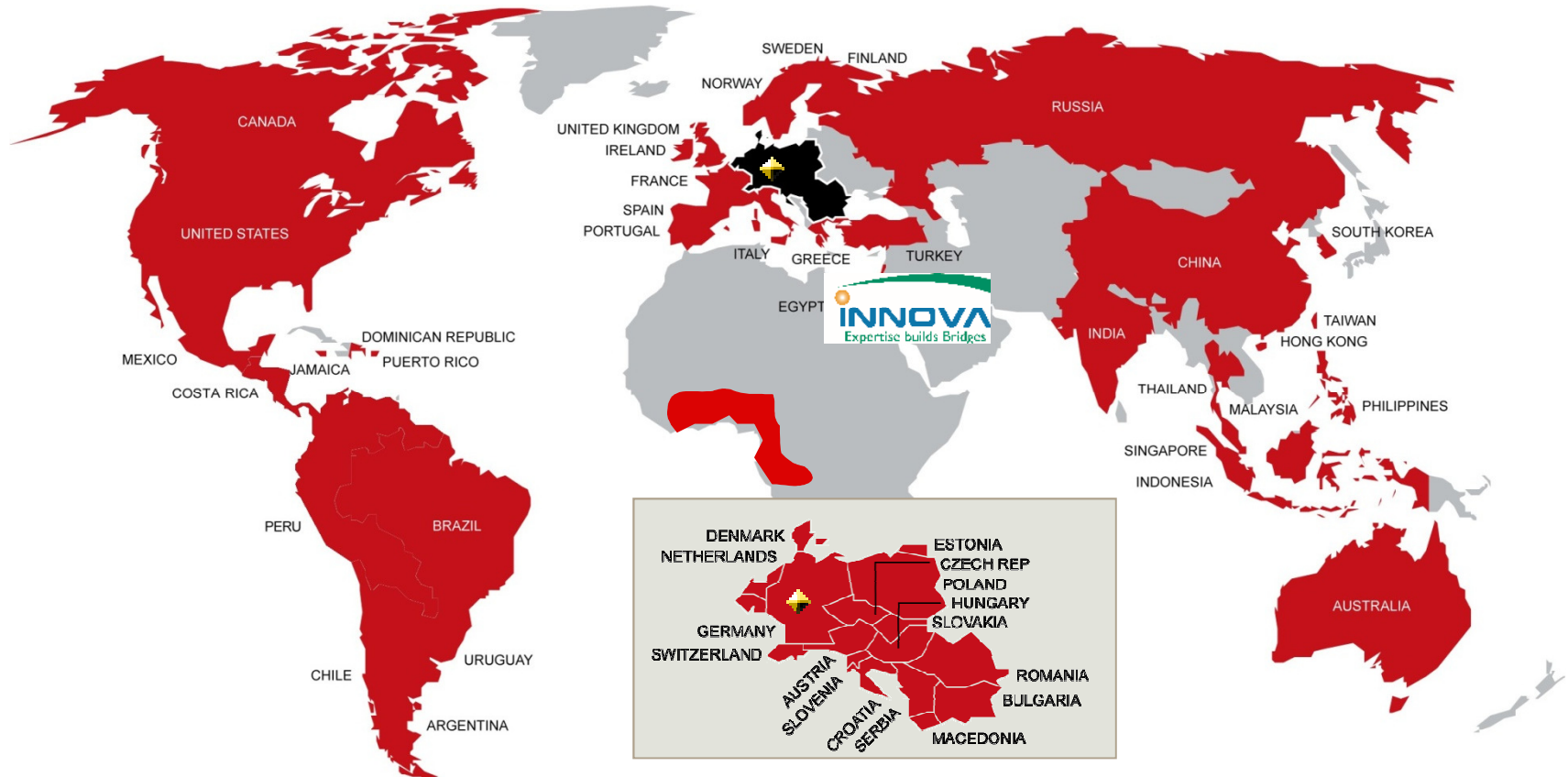
NextPharma



STIFTUNG NERGESUNDHEIT



# Global Reach Experience- conducted studies in 56 Countries



## Data and Technology applied

### CRAFT

**C**linical **R**esearch **A**nalysis and **F**easibility **T**ool

An enabling technology that permits searching of very large databases to support:

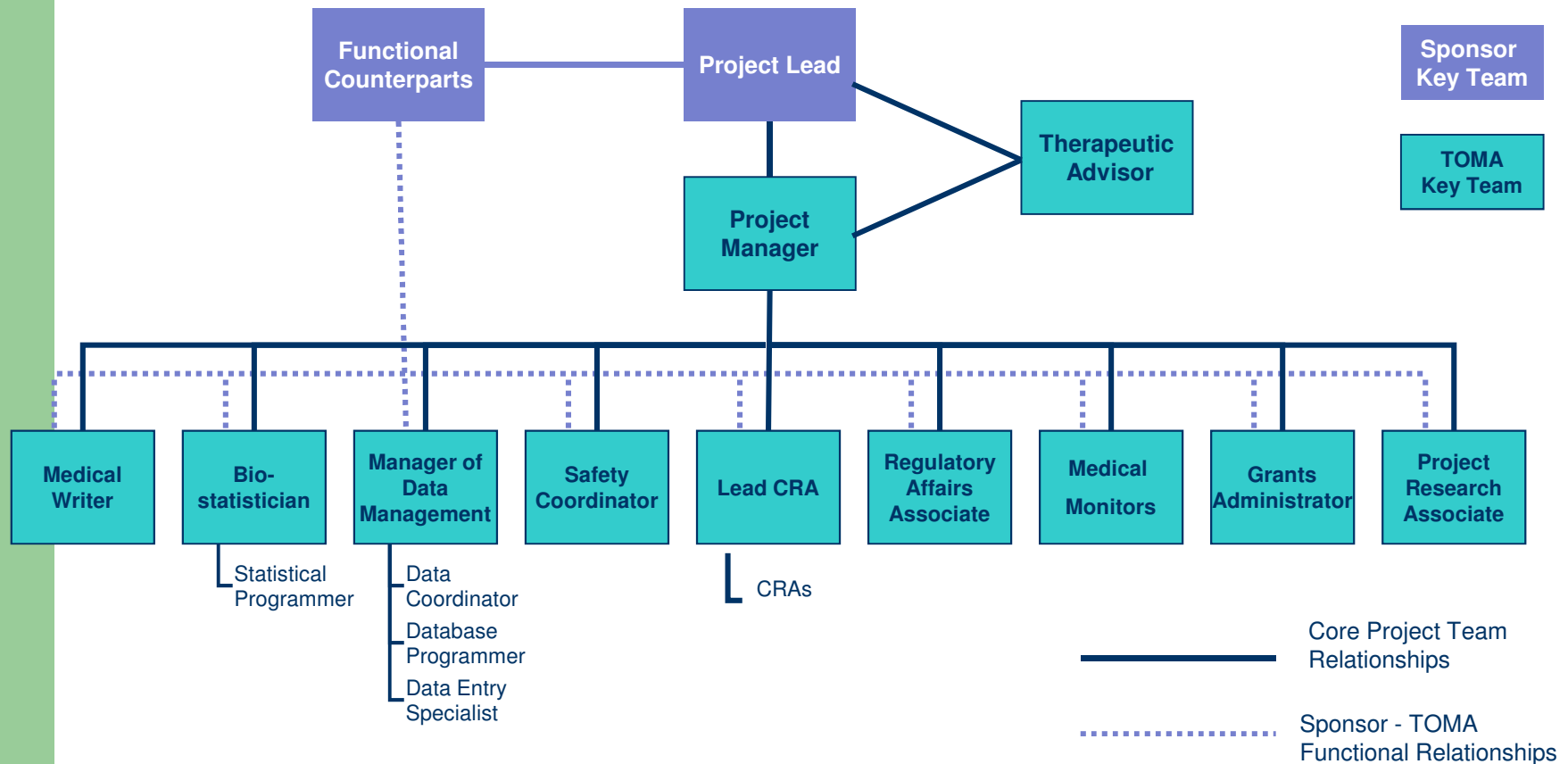
- Identification of available patient populations
  - Patients with specific clinical disorders
  - Patients on specific drug regimens
  - Characterized by age/gender/geographic location/other
  - Other inclusion/exclusion criteria
- Identification of Clinical Investigators
  - Physicians providing care for those patients
  - Subgroup with significant clinical trial experience
- Protocol Design and Feasibility
  - Real time feasibility and “what if” modeling



**LaNova Consulting s.r.o.**  
**INNOVA CTMD**

**Clinical Operations**

# Project Team Structure



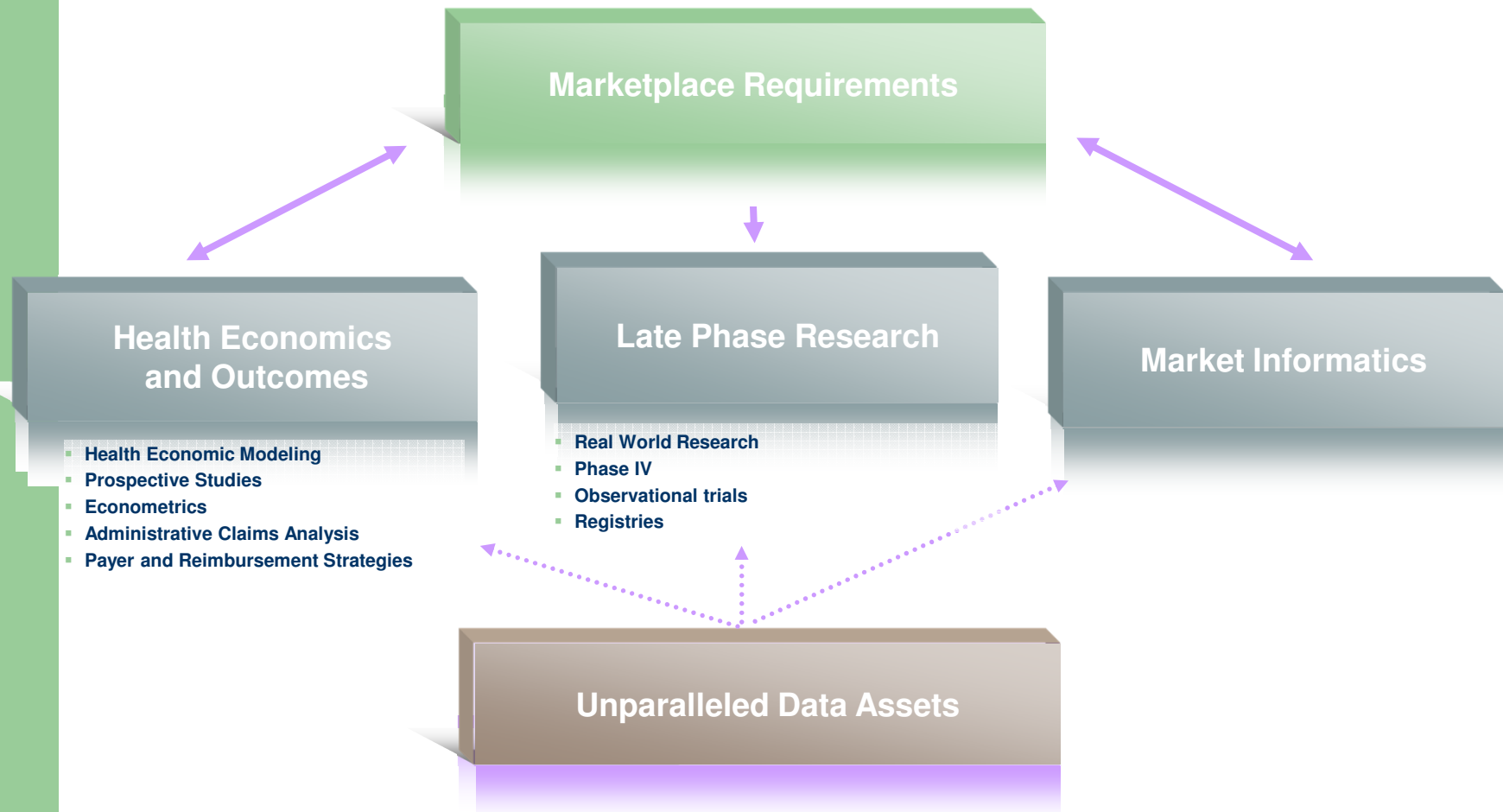




# Capabilities and Services

Phase I	Phase II	Phase III	Commercialization
Contract Research			
Data Services and Biostatistics			
Clinical Staffing Solutions			
Certified Education			
Health Economics and Outcomes Services			
		Market Intelligence	
Drug Safety: Pharmacovigilance and Epidemiology			

# Health Economics Services & Capabilities





## Regulatory Affairs Global Team

### **International Regulatory Affairs Co-operation**

- International Team Member(s) in the Germany, Czech Republic, Switzerland, Jordan, KSA, UAE
- Rest of World CT experience: EU, Eastern Europe, Middle East, South Africa

# Scientific Management

- Scientific management is a variation on the theme of economic efficiency
- Specialization, differentiation, as well as interdisciplinary integration are well-known phenomena in the development of sciences
- It comprises a range of strategies and practices to identify, create, represent, distribute, and enable adoption of insights and experiences. Such insights and experiences comprise knowledge, either embodied in individuals or embedded in organizational processes or practice
- It refers to the planning and coordination of health care services appropriate to achieve the goal of medical science

# Education

## • Master of Science Curriculum

### • Design

The program is designed to prepare

- early and experienced stage researchers,
- academics,
- physicians,
- industry and hospital based researchers

to conduct, implement and interpret Clinical Research at the intersection between basic science and Clinical Medicine.

### • Interface

It is designed to bring diverse disciplines together to address the increasing gap between "bench" research and "bedside" application relating to Medical Research, to improved healthcare quality.

## Research Assoziation

- **ICR – Institute of Clinical Research**

- The Institute of Clinical Research (ICR) is Europe's leading body for clinical research professionals. The Institute aims to ensure and justify public trust and confidence in the services provided by its members by ensuring high levels of technical competence and professional conduct.
- CSO is the German representative of the ICR
- Advocated as member of the European Advisory Board

## Medical Management

- **Flexibility to set up and „run“ Trauma Surgery & Burn Units**

We realize large-scale projects comprising development, erection and management of hospitals in close co-operation with our partners.

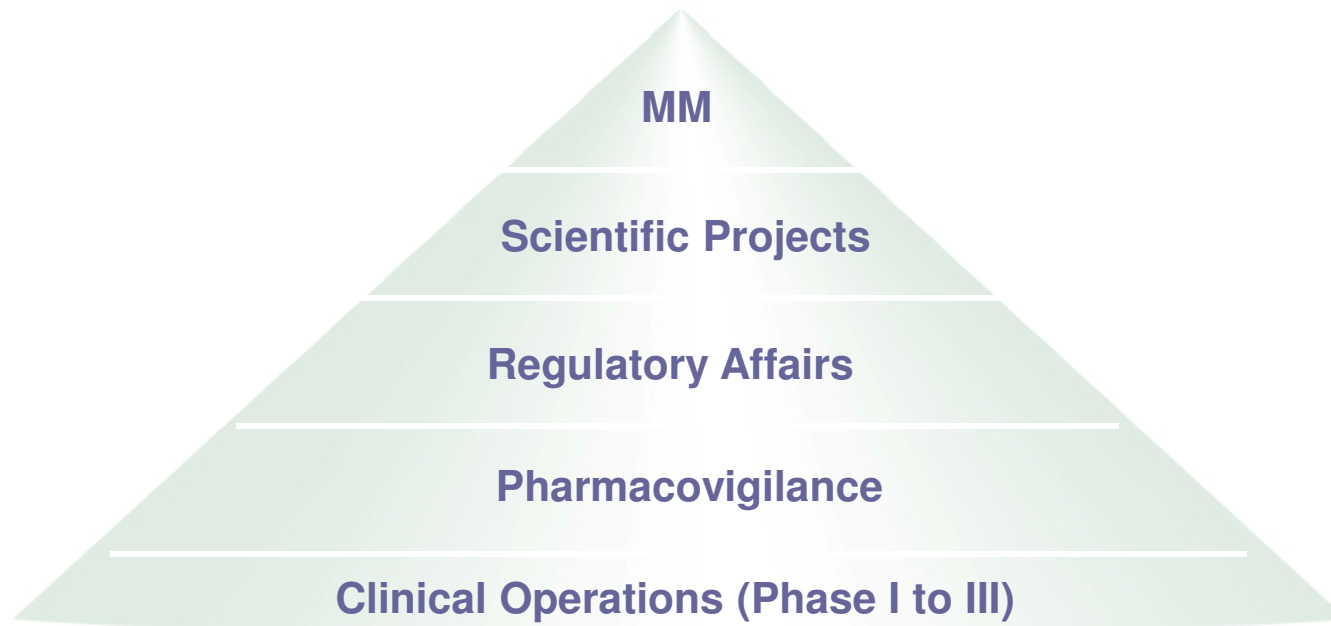
- Consulting
- Supporting
- Implementing
- Managing

of Trauma Surgery & Burn Units due to German standards (KTQ).

# Flexibility



LaNova Scientific



CRO

SMO

SRO



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