



Clinical Center

America's Research Hospital

➤ **NIH serves as the United States' Medical Research Agency**

➤ **27 Institutes and Centers**

- Each with its own disease focus

➤ **Connects NIH researchers and external partners**

- Exclusive/Non-exclusive licenses
- Clinical Validation (Clinical Trial Agreements; CTAs)
- Co-Development (Cooperative Research and Development Agreements; CRADAs)
- Low-cost Tools/Reagents (Material Transfer Agreements; MTAs)



Facts and Numbers:

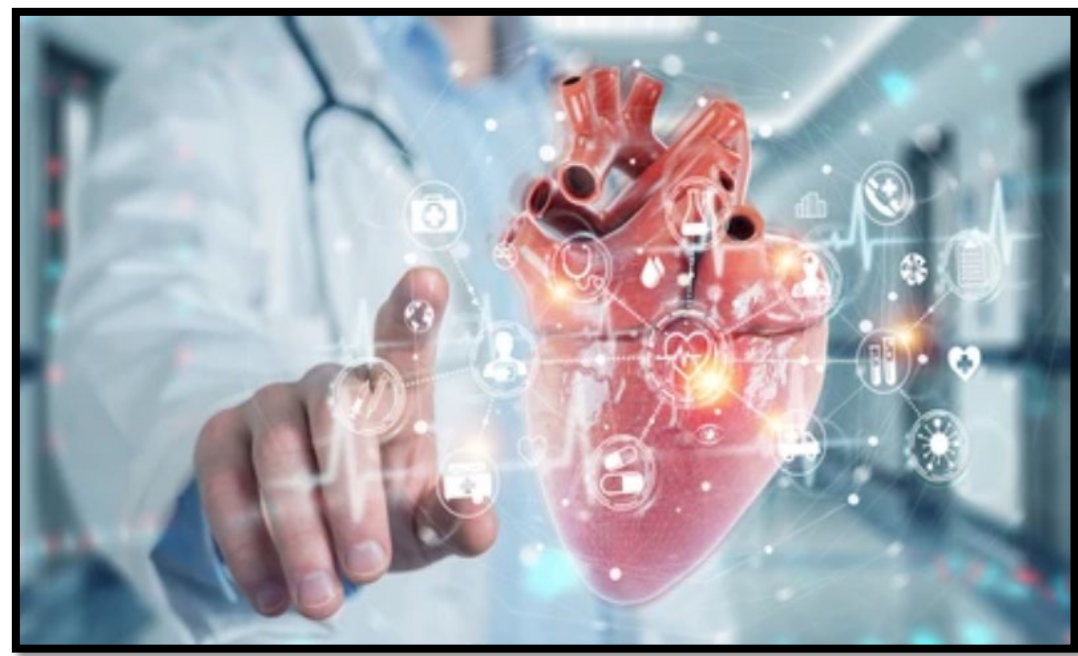
- **World's largest hospital devoted entirely to clinical research (>800 ongoing trials)**
- **World's largest holder of INDs**
- **First-in-human trials emphasizing clinical validation:**
 - rare, orphan, pediatric and neglected diseases/disorders
 - diseases/disorders of high public health impact
- **Developing state-of-the-art diagnostic, preventive, and therapeutic interventions**
- **Investigating disease pathogenesis**
- **Ensuring ethical, efficient, and high scientific quality**
- **15 outpatient clinics**
- **>60,000 annual visits and >3000 in-patient admissions**

AGREEMENT TYPE	Clinical Cooperative Research & Development Agreement (CRADA)	Clinical Trial Agreement (CTA)
Collaborating Parties	Universities/Non-profits/For-profit Companies	Universities/Non-profits/For-profit Companies
Testing & joint development	✓	✓
OWNERSHIP		
• Data generated	Typically the Party that generated it – owns it	Typically the Party generating it – owns it
• Inventions	Inventorship determined by US patent law	Inventorship determined by US patent law
• Licensing (“fair access” considerations)	<ul style="list-style-type: none"> • Collaborator 1st in line; • Provides collaborator an “exclusive option” to apply for a license. • Intent to grant an exclusive license not advertised; 	<ul style="list-style-type: none"> • NIH must advertise opportunity; • “...NIH will seriously consider collaborator’s license application.”
FUNDING		
Funds transferred to NIH for study support	✓	✗

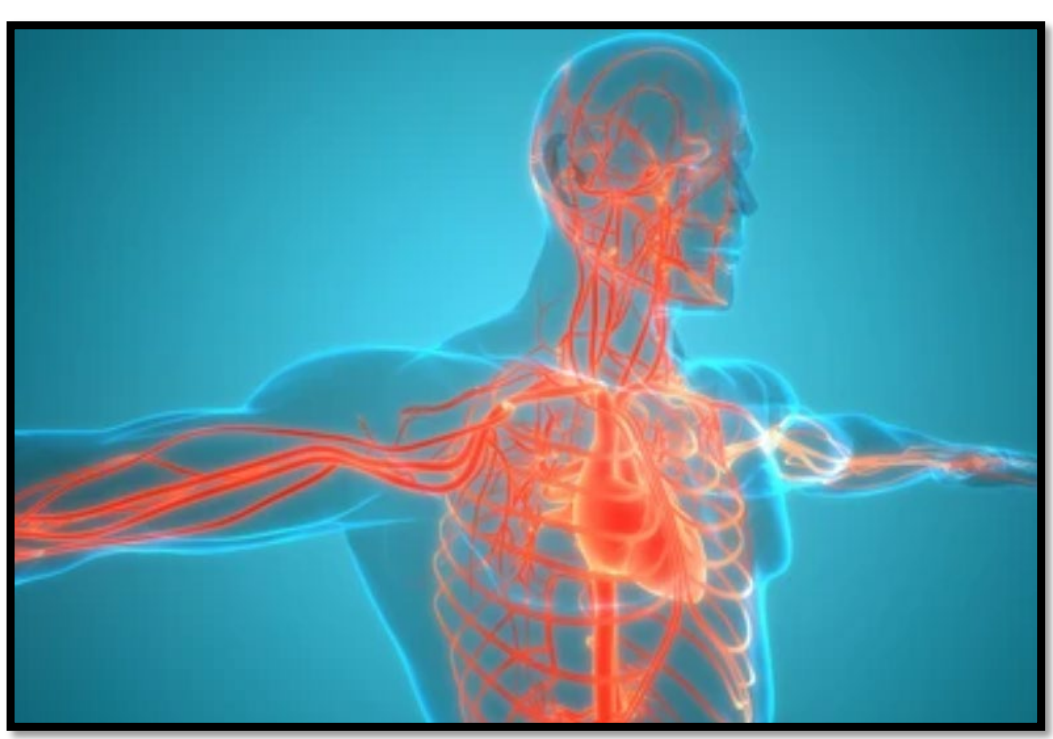
NIH Clinical Center: Scientific Breakthroughs/Firsts



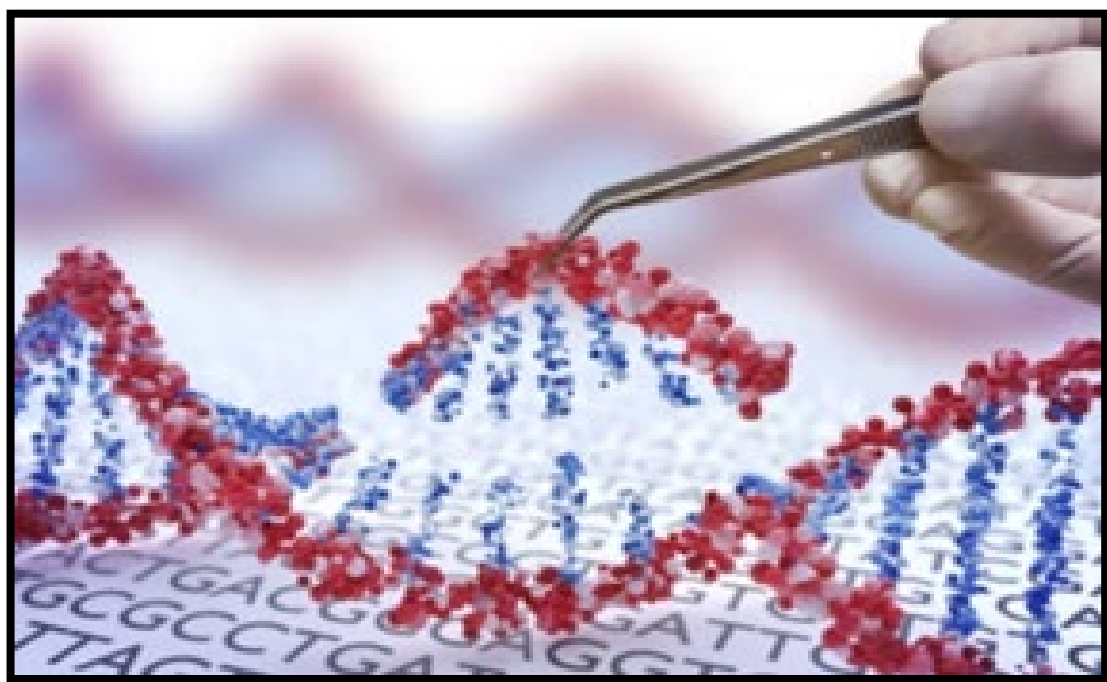
- HPV vaccine to prevent cervical cancers
- Chemotherapy of solid tumor
- Chemotherapy of childhood leukemia and Hodgkin's disease
- Immunotherapy for cancer treatment



- Mitral valve replacement
- Nitroglycerin for acute myocardial infarction
- Analysis of lipid metabolism disorders and pathogenesis of arteriosclerosis
- NMR imaging for rapidly diagnosis of coronary artery disease



- Immunosuppressive therapy for aplastic anemia
- Hydroxyurea therapy for sickle cell anemia
- Immunosuppressive therapy for nonmalignant diseases (lupus, Wegener's granulomatosis, midline granuloma)
- INF-gamma reducing bacterial infections in chronic granulomatous disease
- Reduction of transfusion-transmitted hepatitis to near 0%



- Gene therapy (for adenosine deaminase deficiency)
- Enzyme replacement to treat Gaucher's disease



- AIDS
 - Description of pathogenesis
 - Blood tests
 - AZT



- Computerized hospital information system facilitating clinical research



- Evidence of genetic component in schizophrenia
- Controlled trials of lithium's effect on depression

Websites

<https://clinicalcenter.nih.gov>
<https://irp.nih.gov>
<https://www.techtransfer.nih.gov>

General Inquiries:
nihott@mail.nih.gov

Social Media



<https://www.facebook.com/NIHClinicalCenter>



<https://www.linkedin.com/company/nih-clinical-center-cc/>