

# The Biobank of the National Institute for Infectious Diseases 'L. Spallanzani':

a facility at the service of research on Infectious Diseases

Infectious Disease Biorepository  
National Institute for Infectious Diseases 'L. Spallanzani'  
Rome, Italy



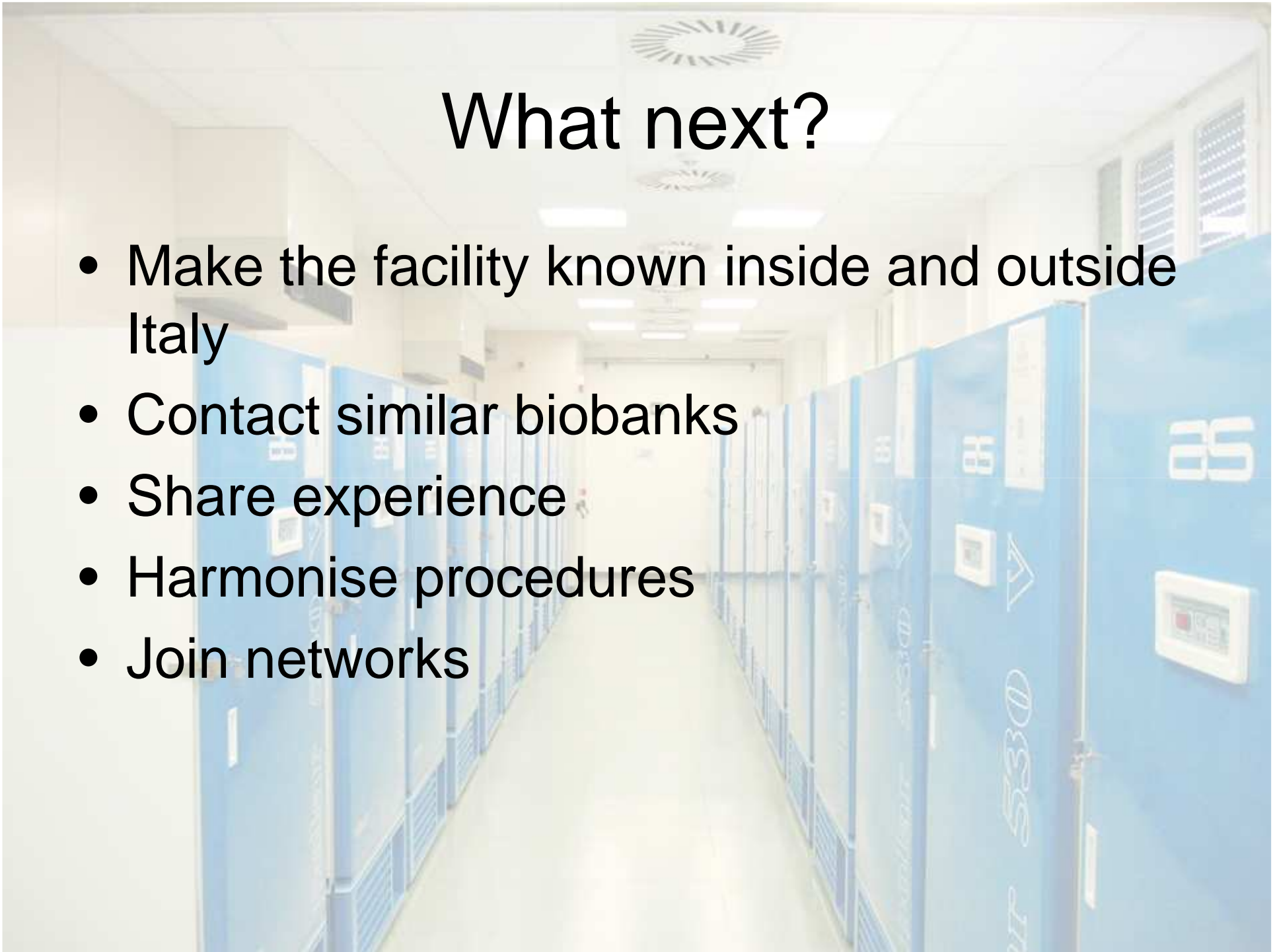
**Biobanks: Introduction and Next Steps, San Feliu de Guixols 1-6 November 2008**

# The Biobank

- Sample collection started end '60s and increased consistently after AIDS epidemic (ICONA, 1997)
- Dedicated facility built in 2001
- Upgrading in 2003
- Certification ***ISO 9001:2000 Quality*** management systems (2004)
- Dedicated, full-time staff employed (2007-2008)

# What next?

- Make the facility known inside and outside Italy
- Contact similar biobanks
- Share experience
- Harmonise procedures
- Join networks





## Historical background

- **1936: Opening of Infectious Disease Hospital “Lazzaro Spallanzani”**
- **Early 90’s: Construction of the new hospital, urged by the AIDS epidemic**
- **1996: Designation as Research Institute**
- **1999: Designation as National Institute for Infectious Diseases (INMI).**

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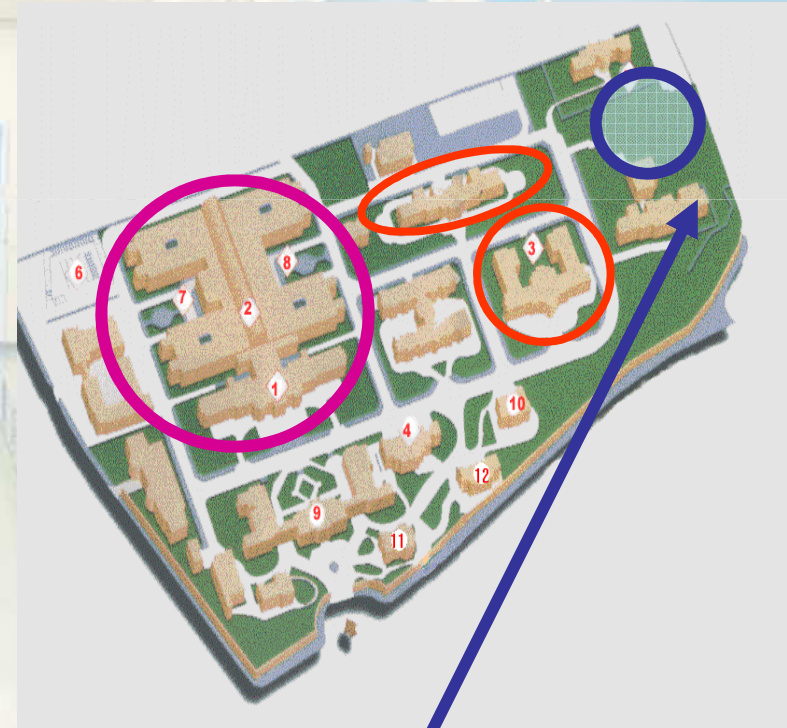


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- **A new building, under construction, will include 10 high isolation units and new BSL4 and 3**





## **MISSION OF SPALLANZANI INSTITUTE**

- **Health care: state of the art clinical care for patients with infectious diseases (HIV, viral hepatitis, severe, emerging/re-emerging infections, immunocompromised host);**
- **Surge capacity: global response to emerging/re-emerging diseases, including highly contagious, naturally occurring and deliberately caused (BT) infections**
- **Translational research: integration between clinical, epidemiological and pre-clinical research with the aim of enhancing the diagnosis, care and prevention of infectious diseases.**





# THE SPALLANZANI INSTITUTE

## Department of **Epidemiology** and **Basic Research**

## Department of **Cinical Research**

- **Infect Dis- Liver Diseases**
- **Infect Dis- Severe Infections**
- **Infect Dis- HIV/AIDS**
- **Infect Dis- Tropical Diseases**
- **Infect Dis- Respiratory infections**
- **Long term care/Rehabilitation**

## Department of **Diagnostic Research**

- **Virology (high containment laboratories)**
- **Microbiology**
- **Clinical Pathology**
- **Biorepository and Tissue Banking**
- **Imaging**
- **Morbid Anatomy**

## Services

- **Hospital Pharmacy**



- **AIDS referral center**
- **Clinical epidemiology and trials**
- **Occupational infections**
- **Observational studies and diseases registry**
- **Cellular biology & electron microscopy**
- **Gene expression & experimental hepathology**
- **Cellular Immunology**
- **Molecular microbiology**
- **Monitoring of antiretroviral drugs resistance**

## Department of **SOT (liver, kidney, pancreas)**

- **Surgery**
- **Intensive Care**
- **Transplant Hepatology**



# The National Institute for Infectious Diseases 'L. Spallanzani'- Italy

## Special tasks

- National Reference Centre for emerging/reemerging viruses and bioterrorism
- Patient care
  - high isolation capacity, high containment ambulances.
- Laboratory Diagnostics
  - BSL-3/4 laboratories
- Research and Training Centre
  - Epidemiological and clinical research on EIDs

# Scope of the Biobank

- **Collection and long-term storage of samples for:**
  - **Research projects;**
  - **Observational studies;**
  - **Clinical trials activated in Spallanzani;**
  - **Mandatory storing of diagnostic samples (forensic or regulatory issues);**
  - **Valuable residual diagnostic samples;**
  - **Serum samples from health care workers involved in special activities;**
  - **Collection of cell lines and viruses (clinical isolates, ref. strains);**
  - **Service for external users**

## Examples of projects/collections

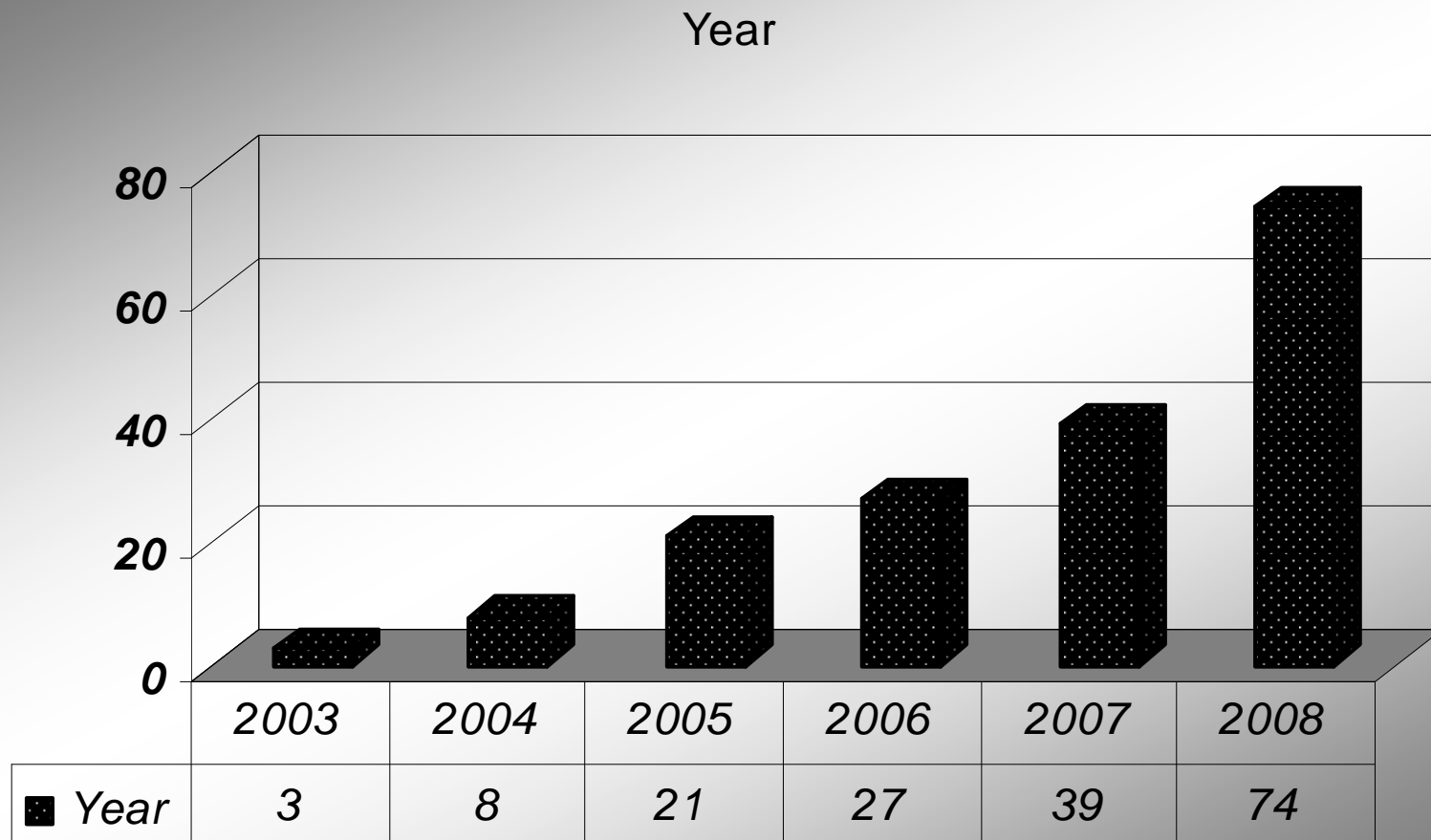
<b><i>Project</i></b>	<b><i>Sample type</i></b>
<b>HIV: natural history and treatment</b>	<b>PBMC and plasma, CSF, genital secretions</b>
<b>Viral Hepatitis: natural history and treatment</b>	<b>Serum, liver biopsy, PBMC</b>
<b>HIV/HCV coinfection: natural history and treatment</b>	<b>PBMC, serum, plasma, liver biopsy</b>
<b>Mandatory collections</b>	<b>HIV-Ab+ sera</b>
<b>Clinical trials (drug efficacy)</b>	<b>Serum, PBMCs, Plasma</b>
<b>Heart diseases and infections</b>	<b>Heart biopsy</b>
<b>Transplanted patients</b>	<b>Biopsies, PBMCs, plasma, serum</b>
<b>Risk group 3/4 viral agents</b>	<b>virus stocks</b>

## Some Numbers...

<i>Sample type</i>	<i>Number of vials</i>
<b>PBMCs (N<sub>2</sub> vapour)</b>	<b>67,000</b>
<b>Hepatitis sera</b>	<b>10,000</b>
<b>Liver biopsies</b>	<b>800</b>
<b>HIV-infected plasma</b>	<b>190,000</b>
<b>Sera tested for HIV-ab (since 1992)</b>	<b>80,000</b>
<b>Valuable diagnostic samples (acute infection sera, IgM+)</b>	<b>1,500</b>
<b>CSF</b>	<b>2,900</b>
<b>Other</b>	<b>2,900</b>
<b>Total</b>	<b>355,100</b>



## Cumulative number of Projects/collections



## **INMI Biobank: Quality assurance**

- **Responsibilities (Staff, Scientific/Ethics Committee)**
- **Project selection**
- **Maintenance (supplier/manufacture)**
- **Incident management procedures**
- **SOPs**
- **Databases**
  
- **Monitoring of environmental parameters (oxygen level; temperature; ventilation)**
- **Monitoring of equipment (temperature and function)**
- **Alarm management (remote system)**
- **Automatic liquid nitrogen refill**
- **Liquid nitrogen backup for -80°C freezers**

## Critical Issues (harmonisation needed)

### SOPs:

- Project/collection activation/identification
- Sample intake
- Sample preparation
- Sample storage
- Sample log and database
- Sample retrieval
- Sample database update
- Sharing of samples

### Training

- ✓SOPs,
- ✓Biosafety
- ✓Incident management (including Basic Life Support)

**Security:** access control, software and DB protection

**Ethical issues:** donors' rights











# **In progress...**

- **Automation (i.e. aliquoting, data transfer)**
- **2D-Barcodes**
- **Service (preparation of ref. Materials for virology diagnostics, proposed collaboration with WHO)**
- **Networking**

## **Future...**

- **New facility: Cell factory for hepatic stem cells**

# Staff

- **Director: Antonino Di Caro, MD.**
- **Fabrizio Carletti, PhD (process control)**
- **Carla Nisii, PhD (quality assurance and networking)**
- **Damiano Travaglini (coordinator of lab technicians)**
- **Roberta Chiappini (Lab technician)**
- **Daniele Khouri (Lab technician)**
- **Fabrizio Petroni (Lab technician)**
- **Alessio Castrogiovanni (Lab technician)**
- **Gianluca Prota (Lab technician)**



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Thank you!