



Clinical Laboratory Services

H3 Africa Repository Project October 2013

Background CLS
Previous Site support / Collaborations in Africa
Repository at CLS
CLS Project Plans for H3 Africa

Dr Ute Jentsch



CLS Entity



Established in 2000

Steve Biko Centre
for Bioethics



University of the Witwatersrand



School of Pathology

Wits Health Consortium

CLS Board
WHC CEO, CFO
CLS CE, COO
HOD School of Pathology



 Wits Pathology Diagnostic Lab	 3 Branches: JHB, CT, DBN Clinical Laboratory Services SANAS, GCLP, DAIDS certified Repository developed as part of our clinical trial services
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Services
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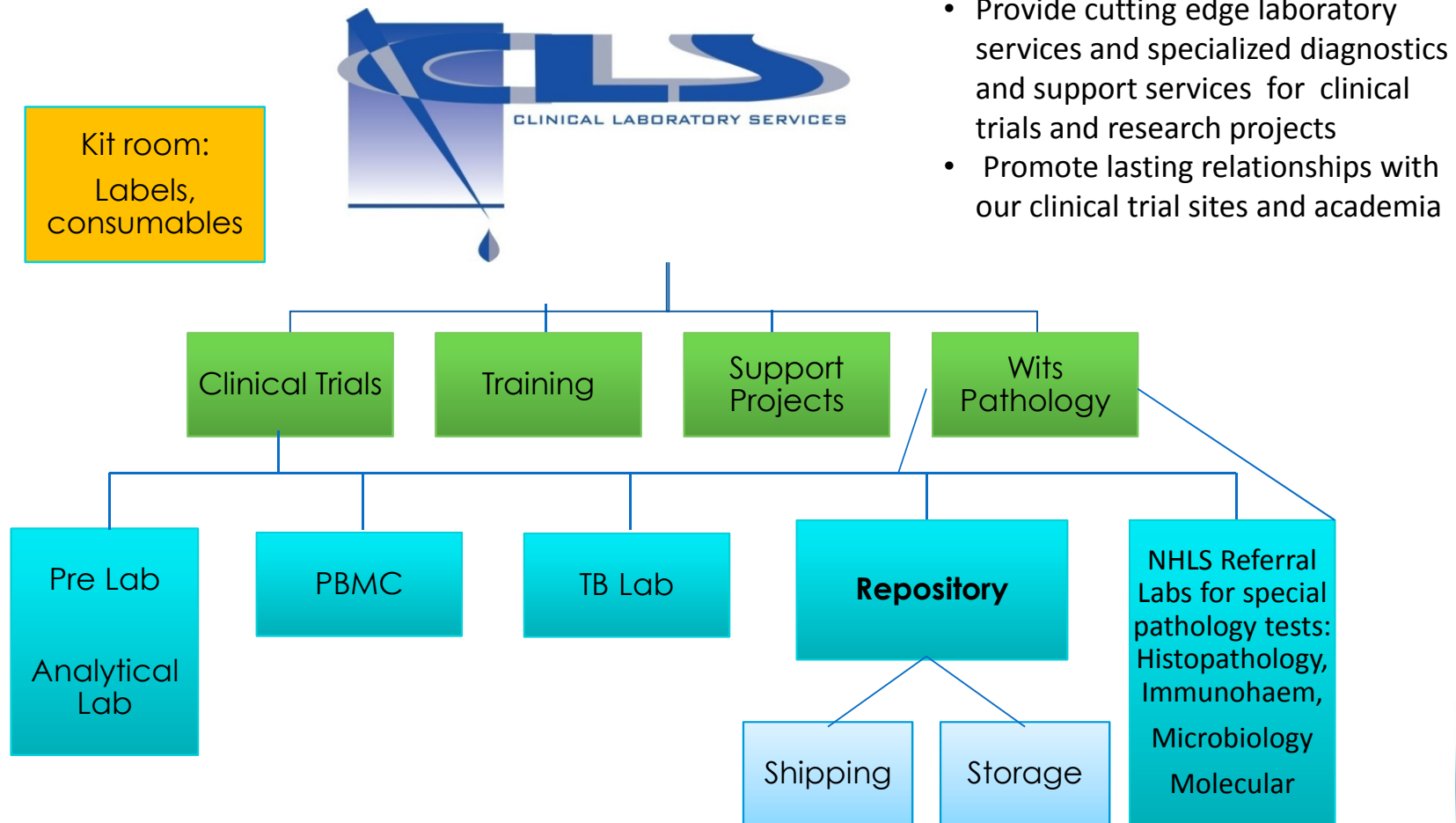
Donald Gordon Medical Centre
(Academic Hospital)

Services
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Clinical Research Sites
260 active studies
holders / 5 WHC sites



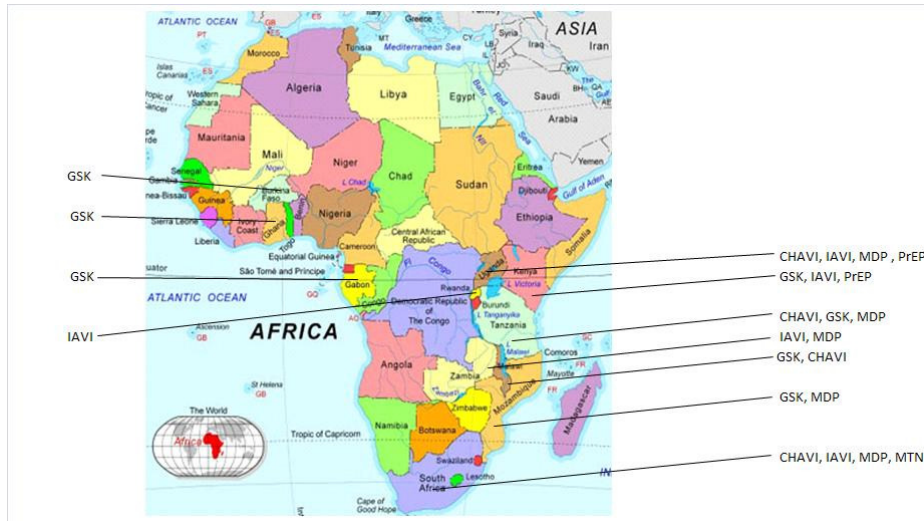
CLS Core Focus



- Provide cutting edge laboratory services and specialized diagnostics and support services for clinical trials and research projects
- Promote lasting relationships with our clinical trial sites and academia



CLS SITE SUPPORT AND COLLABORATION



TRC – Chennai, IAVI
NARI – Pune IAVI

CLS : STRATEGIC LOACTION IN AFRICA

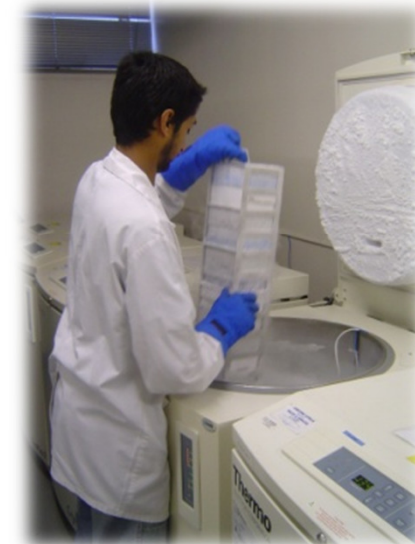
- Central lab for over 900 clinical trials of varying sizes since 2000
- Capacity building in Africa: Provide project and QA support to over 40 sites in Africa and Asia
- GCLP training provided to over 800 delegates locally and internationally since 2003
- Collaborations: NIH networks, Microbicides Networks, IAVI, GSK Malaria Vaccine network, Gates funded (PIP, PreP), TB Alliance

Current Specialized Repository Services

- Repository services provided for most Networks mentioned
- Currently storing about 900 000 samples under strictly controlled conditions
- Laboratory Data Management System (LDMS – Frontier Sciences) used for data management and sample storage.
 - Allows sample data import and export
 - Mapping of all samples
 - Real time updating of sample movement
- Bar code labeling specimen tracking system
- Our Repository manager has also completed the “train the trainer” for LDMS with Frontier Science in US last month (March 2013).
- Operations is run according to GCLP, IATA , accreditation standards, study protocols
- 10 member experienced team all GCLP and IATA trained
- Collaborate with Biomedical Research Institute (USA) and IAVI Core lab Repository (UK)



VISUALS OF OUR BIOREPOSITORY



CLS Repository capacity

	Cold Rooms Refridgerator 2- 8 degrees C)	Walk in – 20 degrees C Freezer	Minus 80 degrees C Freezers	LN2 Freezers (-150)
Number	2	2	40	7
Capacity / unit	200 000 each	100 000 each	40 000	20 000
Current total no of samples (Approx)	Free Capacity	Samples temporarily stored for 7 days.	9360000	77000
Free Capacity	200 000	100 000	200 000 Backup Freezers Available	2 units free . 1 is for back up.
Types of Samples	Reagents Temporary storage of samples	Serum and WB	Serum ,Plasma, Culture extracts, DNA extracts , genital specimens	PBMC's , cells



Monitoring and Risk Management

Monitoring Systems / Risk management:

Main Risks in our location:

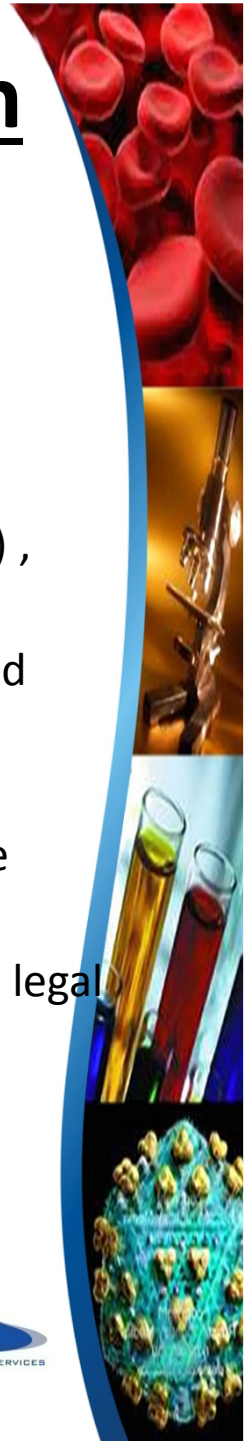
- Power surges / outages

- 24 Hour monitoring via SMS alert
- Back-Up Generator Power
- Carbon Dioxide back up
- Voltage regulation
- Ambient temperature and gases monitoring
- Empty back up freezers and LN tanks
- Disaster Recovery Policy



Staff Safety and Protection of Human Participants

- Biometric access control
- Protective Clothing
- Health and Safety Inspections
- Access to First Aid
- Repository staff members are trained in GCLP, IATA , Frontier Science (LDMS) , LIMS, NIH protection of Human Participants
- Only store samples generated through approved protocols by local ethics and MCC
- CLS stores samples on behalf of its clinical trial partners and does not have authority to distribute these samples to other parties other than through the Principal Investigator / Sponsor for each study with Ethics approval.
- CLS operates within a well-defined legal and contractual framework via WHC legal and grant department
 - Security of information and Confidentiality
 - Customer has title to Work products eg (raw data, source documents generated through our service)
 - Financial management



International Shipment Coordination

- Accounts open with all major courier companies (mostly: World Courier, Marken, DHL)
- Assistance for sites with preparation and shipments to Central Lab's.
- All shipping and repository staff IATA trained
- Managing of Import and Export Permits.
- Experienced in Liquid Nitrogen shipments to international sites in The US, UK and rest of Europe.



Repository Expertise:

- Experience in holding and handling large number of samples for about one decade
- In-bound and outbound
 - 60 outbound shipments / month
 - 25 000 LDMS entries / month
- Custodian of samples for various Networks:
 - ACTG, IAVI, CHAVI, CIPRA, HPTN, HVTN, IMPAACT, FACTS, MTN, MDP, NHLS Cancer Registry
- Managed CHAVI repository and successfully moved over 200 000 samples to US recently.



Dry Shipper for 200 000 CHAVI samples shipped in batches



CLS H3 AFRICA TEAM



DR U Jentsch PI



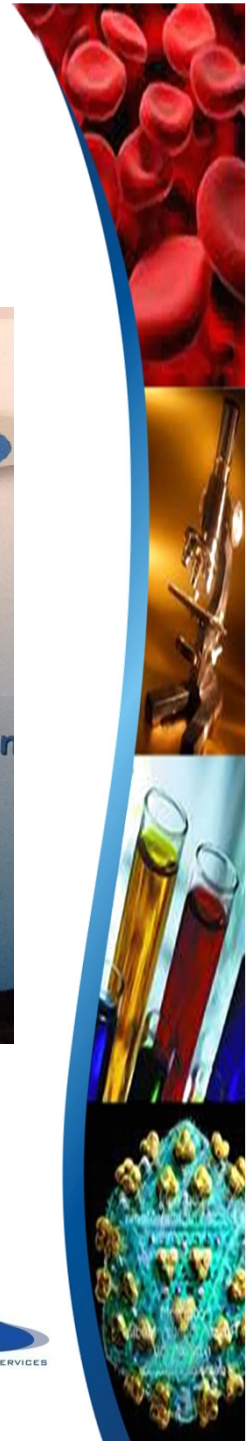
Garth Swartz
Repository Manager



Mukthar Kader
Med Tech / Project manager



Shiksha Reddy
Med Scientist / Operations



Project Plans for H3 Africa : Phase 1

**NEEDS ASSESSMENT AND FOSTERING
COLLABORATIONS**

PROVIDE BIOREPOSITORY CAPACITY

**ENHANCE OUR CAPACITY AND ENSURE THE
H3 AFRICA BIOREPOSITORY NEEDS CAN BE
MET.**

TRAINING



Phase 1: NEEDS ASSESSMENT AND FOSTERING COLLABORATIONS:

Develop processes that will address the needs of the H3 Africa Biorepository functions in a cost-effective and user friendly manner.

Ensure that local and H3Africa regulatory compliance and governance is embedded.

Be an active team member in the BR network structure. CLS will endeavor to develop and strengthen networks and collaborations with other H3Africa Biorepository and Research Sites.



Phase 1: PROVIDE AND ENHANCE EXISTING BIOREPOSITORY CAPACITY

CLS can immediately provide BR capacity. The initial capacity required can be incorporated into our existing infrastructure.

Ring fenced space in our existing repository with required infrastructure to serve H3 Africa .

ENHANCE OUR CAPACITY and the ring fenced space for H3 Africa in our BR. This includes the final scoping of the required storage facilities, evaluation of new software for sample data management and sharing, feasibility of proposed robotics system and novel sample labeling methods.



Phase 1: TRAINING

TRAINING: Internally (and also consider across BR) to CLS H3Africa staff to ensure operations are in keeping with the required standards.

The training will include: LDMS, LIMS, IATA, and GCLP, sample handling and equipping staff with the required theoretical knowledge and practical exposure relating to the repository, health and safety and H3 Africa policies and procedures.



Project Plans for H3 Africa : Phase 2

Scale up and address best practice with respect to sample anonymity, data and sample stewardship by the introduction of new technologies / innovations as partial solutions.

Expansion:

Equipment and additional Human resources

At all CLS sites as required in terms of project needs

Commissioning and Operations: Volumes - receipt and storage of 100,000 samples per year; distribution - of 50,000 samples per year to H3A collaborators depending on demand. According to RFA.

Innovations and collaborations: Enhanced preferably standardized LIMS systems, Robotics System, and novel sample tracking methods (Micro-chips, pre-barcoded cryovials)

CPGR
Other H3A
collaborators



Innovation: Automation using a Robotics System

Hamilton Storage Technologies' BiOS is a scalable-capacity -80°C automated repository for the storage and management of sensitive biological samples.

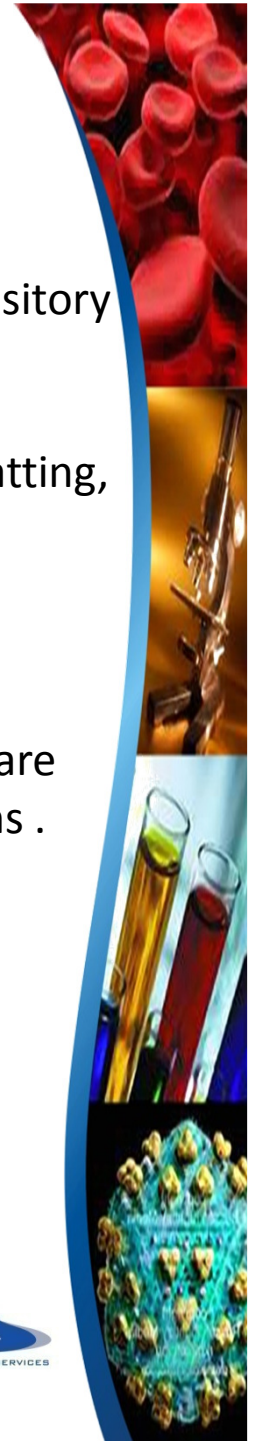
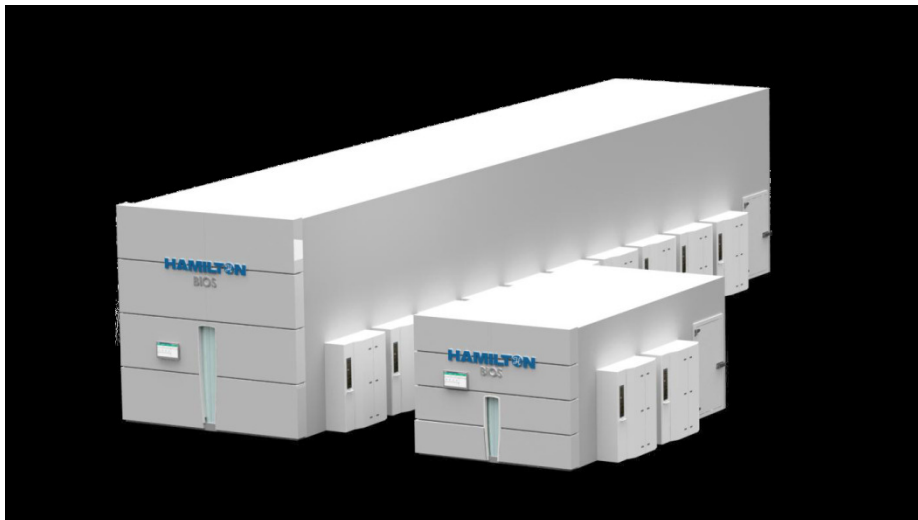
Three key fundamentals:

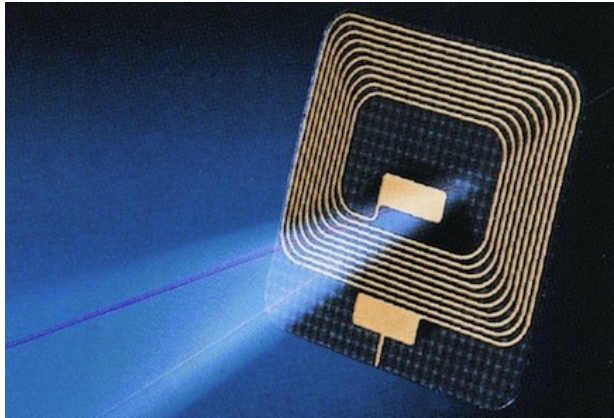
Flexibility: flexible storage format, universal -80°C picker, provides library formatting, can be scaled up.

Sample Integrity and Temperature stability is accomplished by highly insulated sample handling devices, -80°C sample picking and processing in a closed system

Reliability:

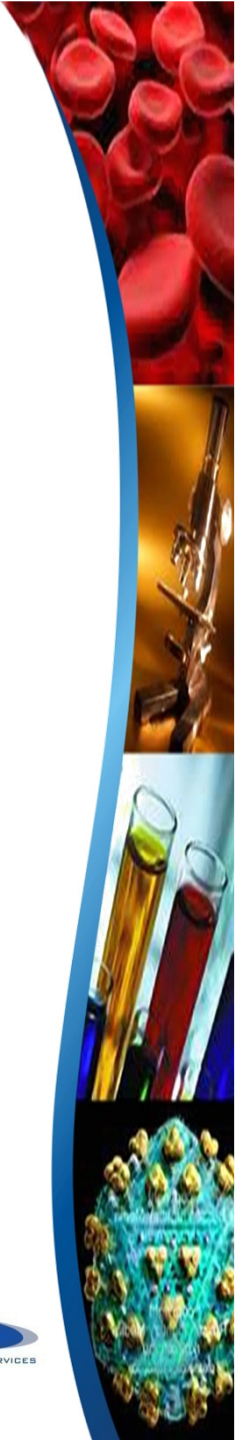
Refrigeration systems can be serviced outside of the machine while the samples are maintained at -80°C in their sealed chest compartments. Frost prevention systems .





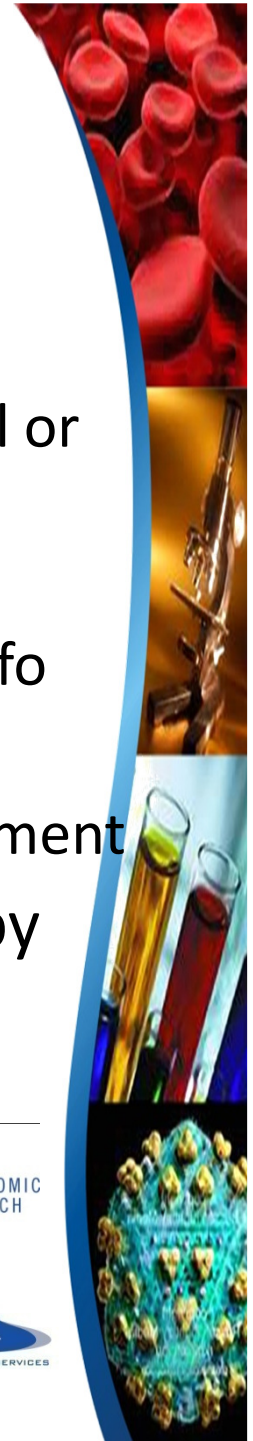
PATHOLOGY
Science Driving Results

CLINICAL LABORATORY SERVICES



Example: Sample labeling and tracking CPGR / CLS Collaboration

- Radio Frequency Identification (RFID) tags:
 - either built directly into the collection vial and cryovial or incorporated into the label
 - Contain stored information
 - Wireless use of RF electromagnetic fields to transfer info
 - would eliminate much of the handling requirements
 - scanned in-situ in the temperature controlled environment
- CPGR (a H3A Bionet Node Site) would collaborate by identifying a small project to pilot this technology
 - Costing and efficiency for H3A in Africa
 - User-friendliness
 - Other alternatives



Key messages for successful H3 Africa Biorepository Projects

- Partnerships / Communication with H3 Africa collaborators
- Standardization: Documentation, IT systems and processes, training
- LIMS :
 - evaluate if BR systems can interface in order to import and export data.
 - Interface with Central Data House
- Overarching Risk management plan
- Exploration of cost efficiencies
- Capacity building and training: LIMS, IATA, GCLP
- Compliance with local and H3 Africa governance requirements.





“Twenty years from now you will be more disappointed by the things you didn’t do than by the ones you did do. So throw off the bowlines. Sail away from the safe harbor. Catch the trade winds in your sails. Explore. Dream. Discover.” -Mark Twain

