



Global Centers for Biological Resources: the Coriell/BioRep Experience

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November 5, 2008

Presentation Outline

- Organization
- Background & Rationale for European Expansion
- Partnership Engagement
- Contracting Opportunity
- Current and Future Biobanking “Drivers”
- Conclusions, Questions & Answers



Introduction to the Coriell Institute

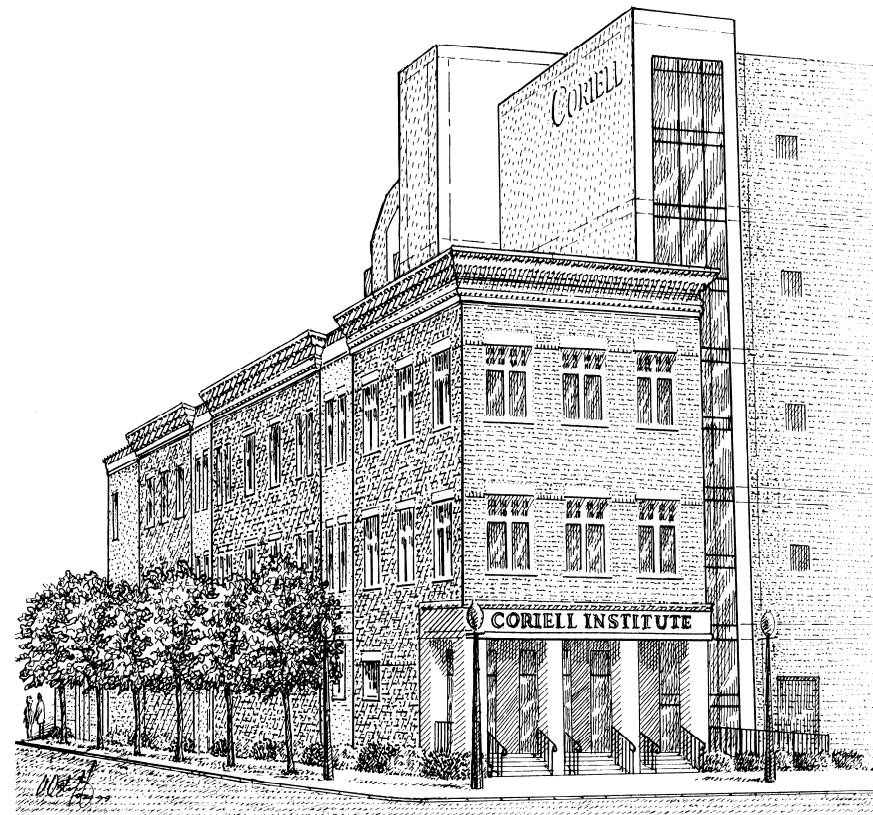
Founded in 1953

Private Not- for- Profit, 501(c) (3)
Corporation

Basic bio-medical research Institute,
committed to basic biological
research, biobanking, and education

Research focus: genome informed
medicine, operationalized through the
“*Coriell Personalized Medicine
Collaborative (CPMC)*”

Home of the *Coriell Cell Repositories* -
the world's largest repository of living
human cells for use in research.



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International Biobanking Experience

- Ships and receives specimens from 40-60 countries annually
- Site of the National Institutes of Health (NIH), National Human Genome Research Institute's (NHGRI) "Haploid Mapping Project"
- Manages public and private collections
- "Custodian" for these and other private collections, assuring compliance to the wishes of the collection sponsor.
- Recognized for its uncompromising commitment to quality.



Expansion Rationale

- Coriell negotiated a large pharmaceutical agreement
- Completed a corporate/intense QA/QC Audit
- European strategy compromised contract execution

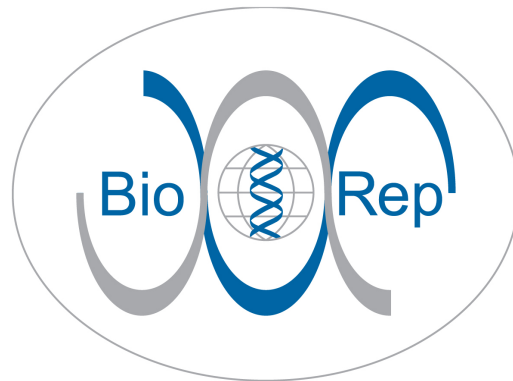


Global Initiative Strategy

- International Partnerships
- Application of ISO9001:2000 standards
- Driven by a commitment to excellence in biobanking
- Information Technology would serve as the central “backbone”
- Specimen management would be achieved via laboratory design
- Unwavering compliance to EU/US regulatory requirements



Negotiated an international
collaboration with BioRep S.r.L.



facilitating research worldwide

Introduction to BioRep

- Founded in 2003, initiated operations December 2005
- Private, Independent biorepository service provider
- Committed to basic biological research, biobanking, and education
- Home of the *EuroHD Network* - the world's first BioBank for Huntington's Disease
- Investors: Sapio Life, Angelantoni Industries, and Integrated System Engineering





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Global Partnership

Purpose:

Extend biobanking services to the international market



Camden, NJ
USA



Milano,
Italy

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Contractual Agreements

Licensing Agreement



Services Agreement



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Essential Terms Licensing Agreement

- Long term Agreement (2015)
- Non-transferable, non-sublicenseable, limited license to Coriell “know-how”
- Exclusivity: EU Countries (2004)
- Availability of Services – “24/7”
- Digital data collection and transmission
- Ownership of Intellectual Property
- Confidentiality
- Compliance with Law/Jurisdiction



Essential Terms Services Agreement

- BioRep: Plan, Develop, Open, and Operate the Lab
- Coriell: Provide “start-up” services
- On-Going Services: Consultation, Training, and Compliance Auditing
- Reporting, Performance & Accreditation
- Independent Contractors
- Assignment and Subcontracting
- Conflict of Interest



Global Partnership

Coriell/BioRep negotiated an agreement with the
HIGH Q FOUNDATION



In Europe:
Euro HD Network
(European Huntington's
Disease Network)

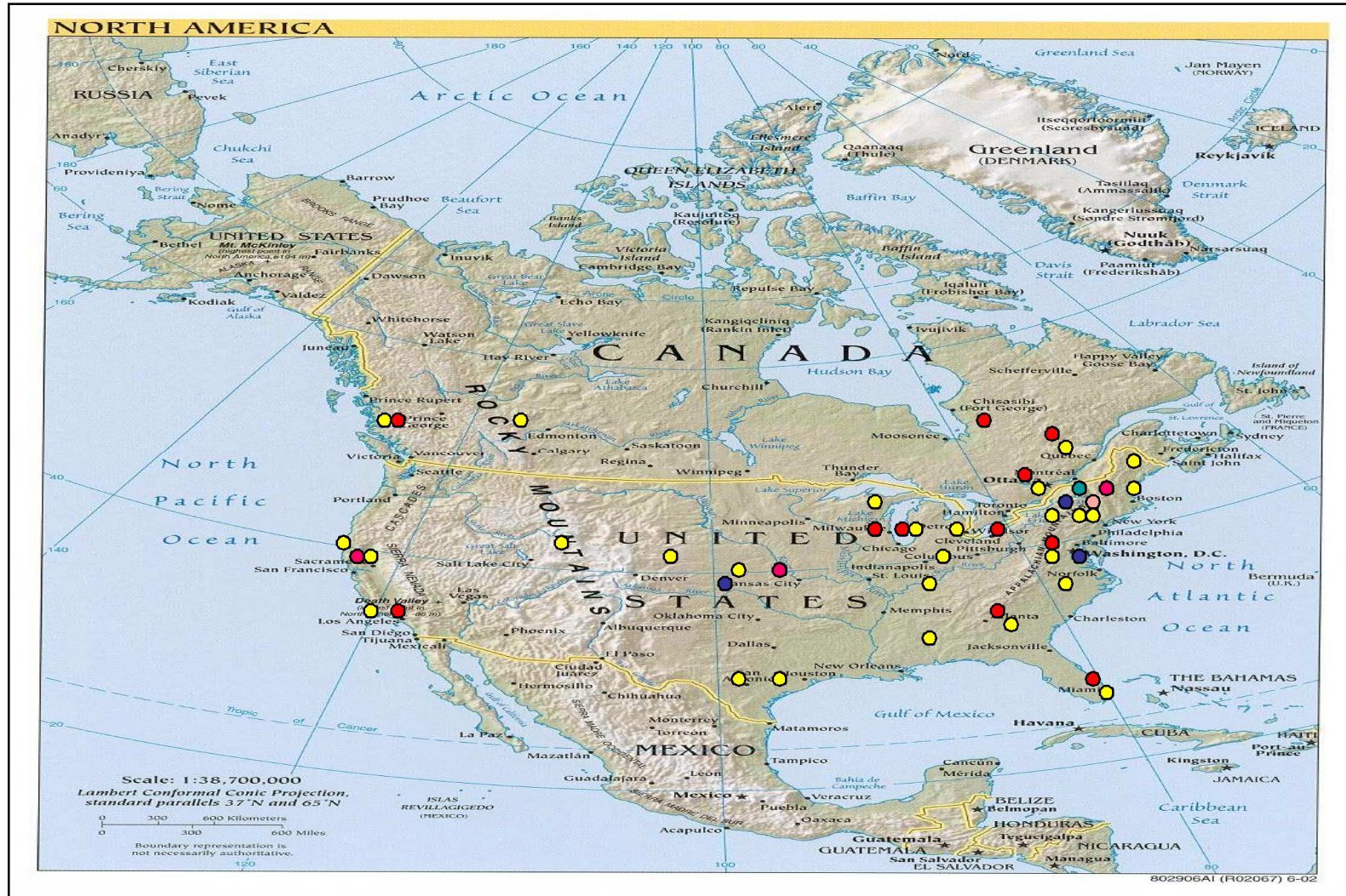
In the United States:
COHORT
(Cooperative Huntington's
Observational Research Trial)





COHORT

(Cooperative Huntington's Observational Research Trial)

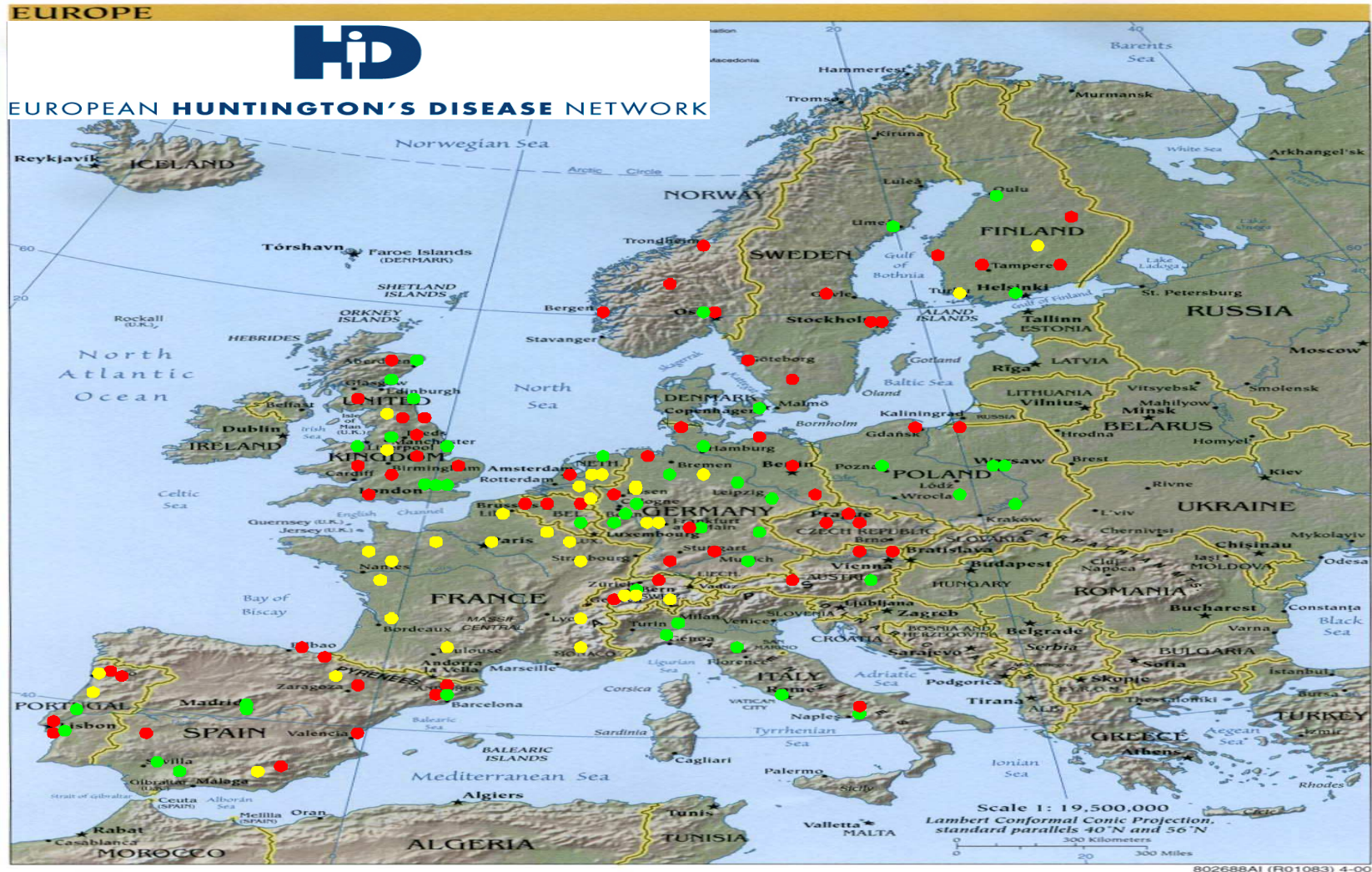


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Courtesy: J. Pallies



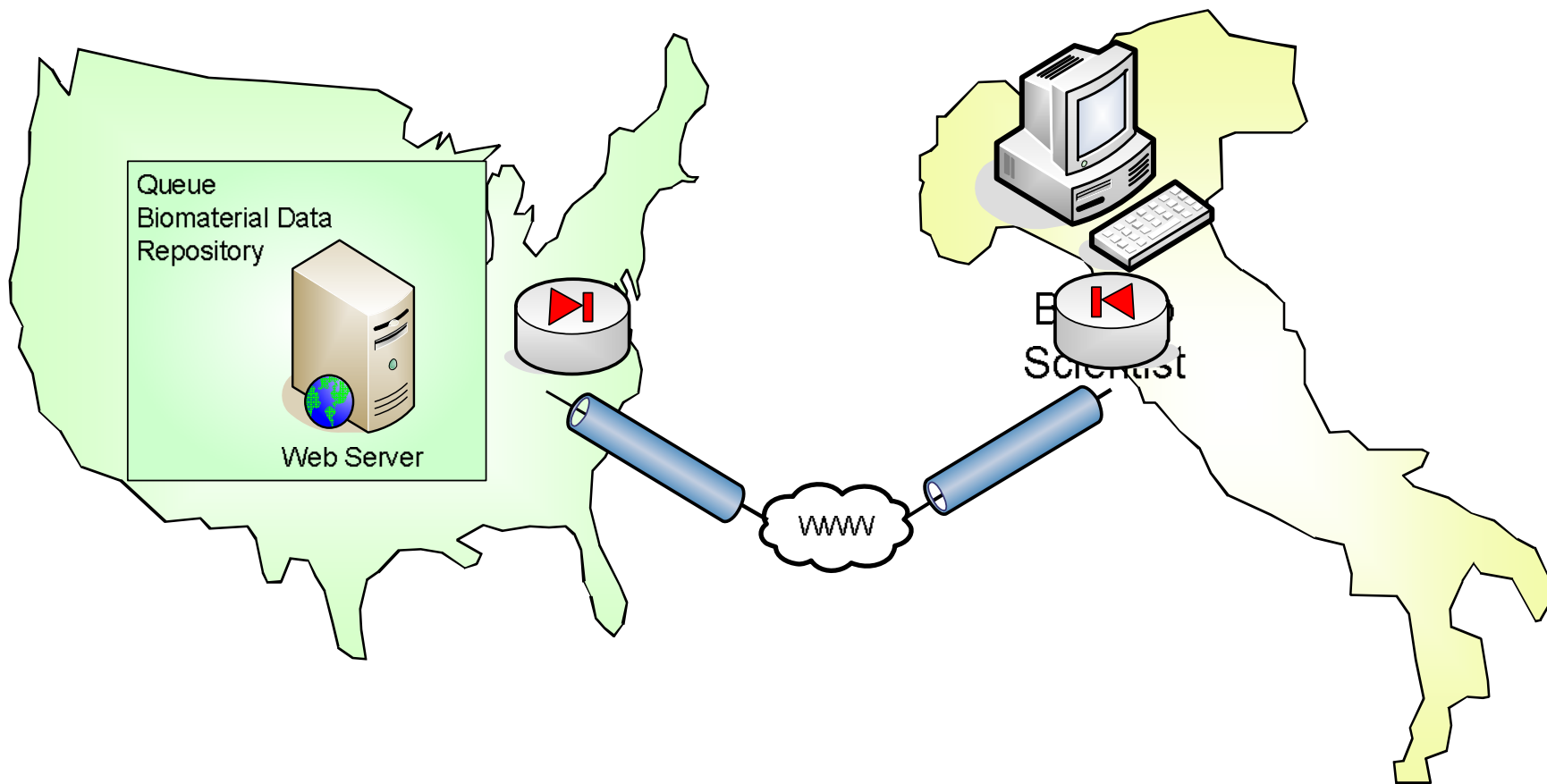
Euro HD Network



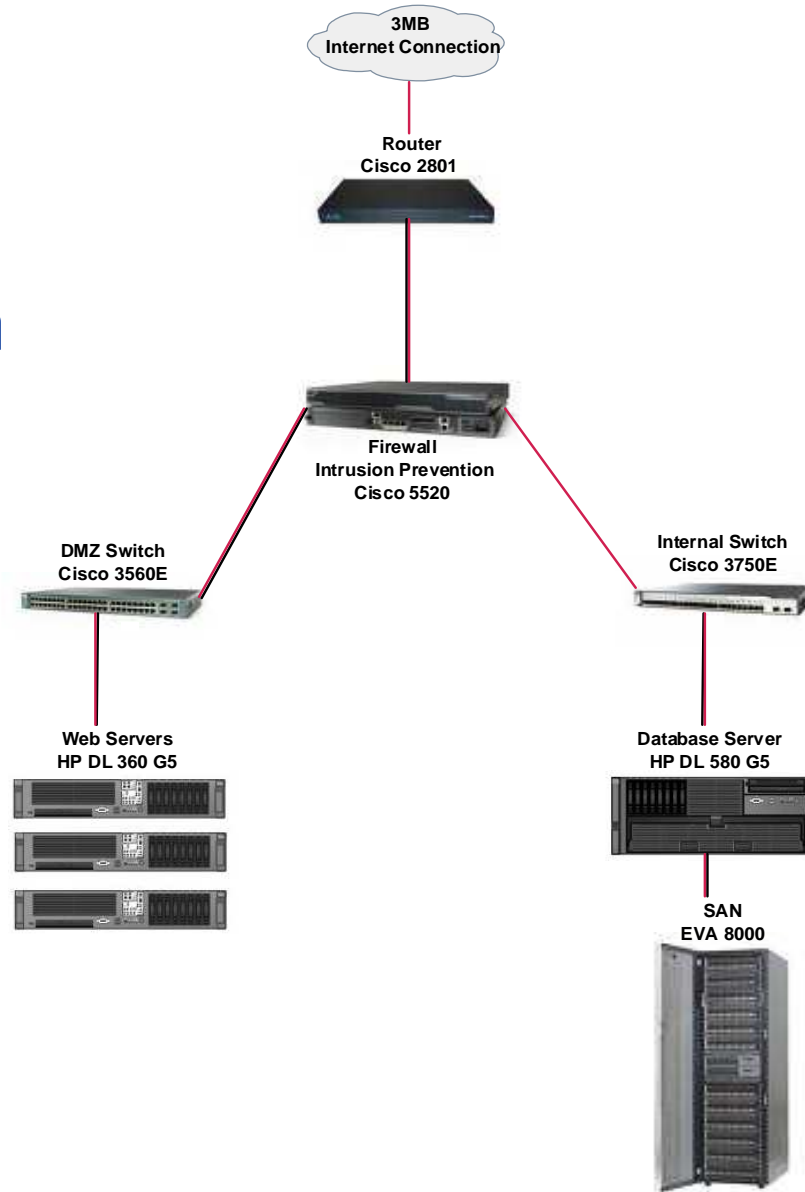
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Courtesy: P DeBlasio

Informatics Infrastructure



Hardware Design



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Courtesy: F. Nash

Coriell's Node on the Internet

Design Objectives:

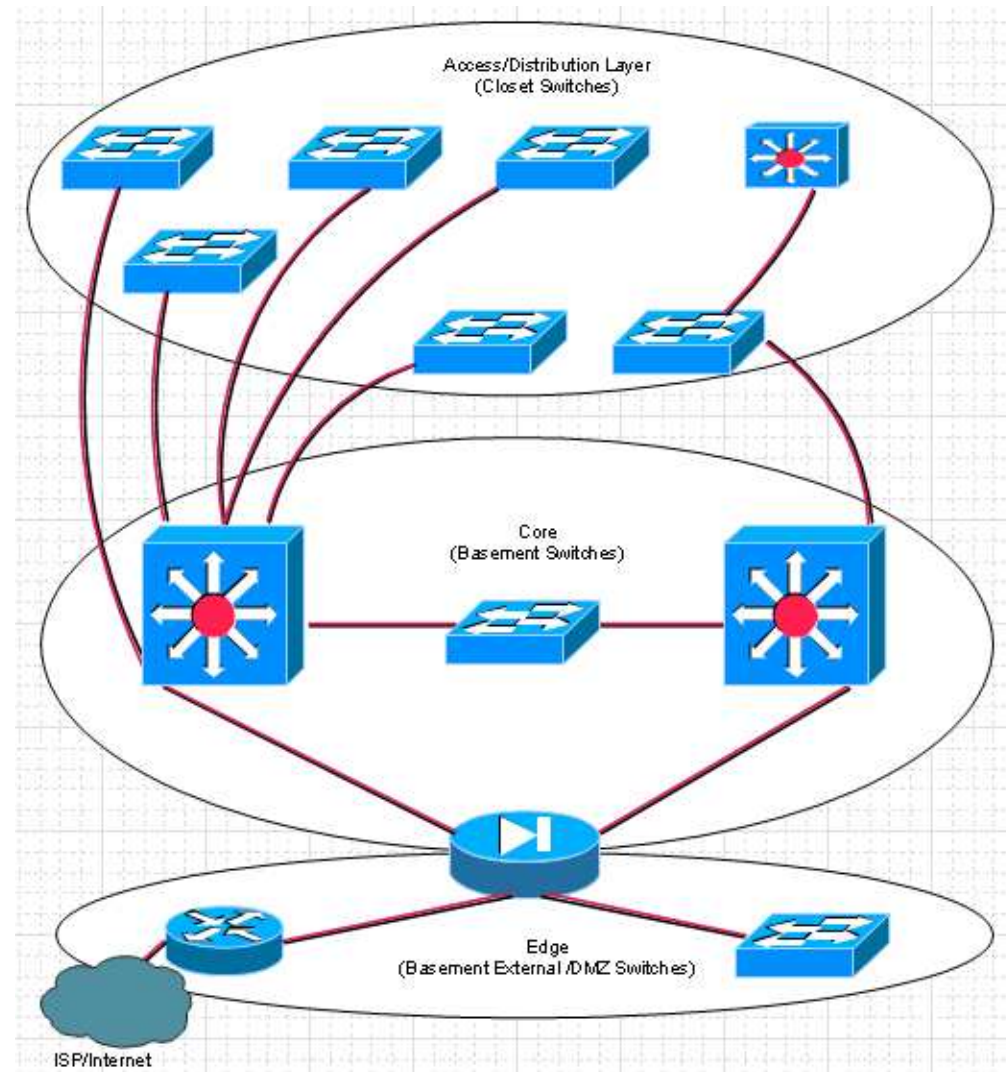
Scalability - provide dedicated network for science programs

Security (industry-standard procedures, VPN, HTTPS, auditing, intrusion prevention)

Speed (1GB/sec switches, traffic prioritization)

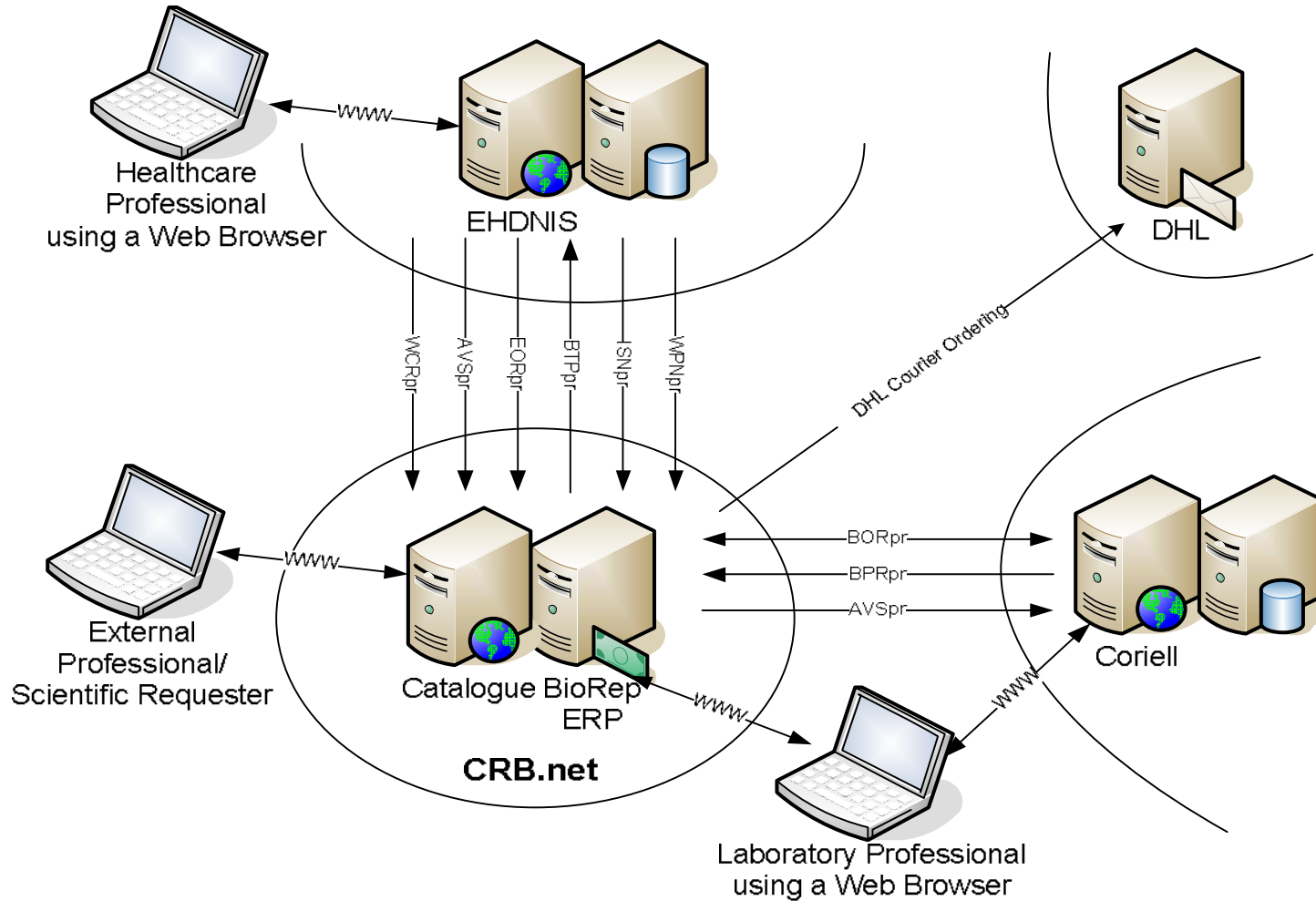
Stability

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EuroHDNET - Web Services



Queue “Q” at Coriell

Queue system is built upon a scalable, web-based architecture, capable of supporting distributed multiple repositories and processes.

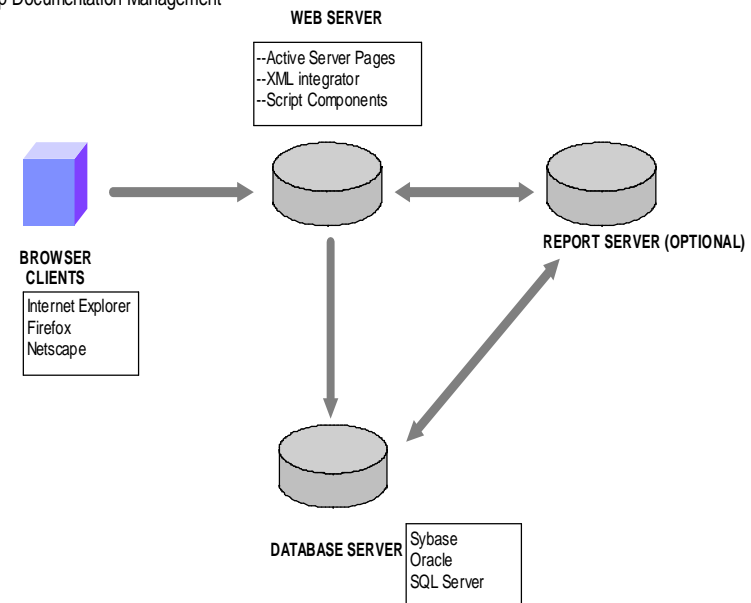


It is evolving from a repository management system to an Enterprise Resource Planning system:

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QUEUE SYSTEM

- Content Management
- User Interface Processor
- Security Management
- Help Documentation Management



1. Integration of data and processes
2. Unified data base used to store data for the various system models

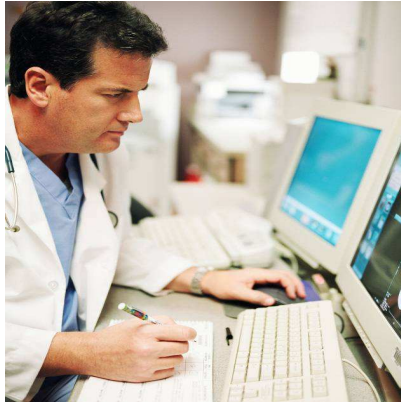


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Considerations for Biobanking in the Future



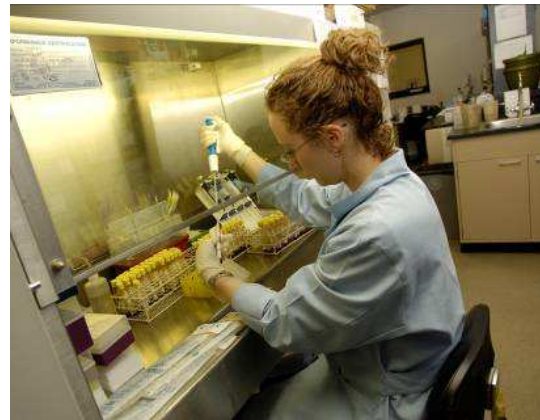
Specialized Collections -
Clinically and Scientifically
Relevant



Technology
Applications



Pharmaceutical
Contracting



Quality Focused



Bioinformatics

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Considerations for Biobanking in the Future



Data Sharing



Specimen Annotation

Virtual Banking



Partnerships

Human Subjects
Engagement





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Considerations for Biobanking in the Future



Health Disparity &
Diversity Collections

Education



“Bridge” to Discovery



Secure Financing

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Acknowledgement

Coriell Institute
Facility and
Staff

2008



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