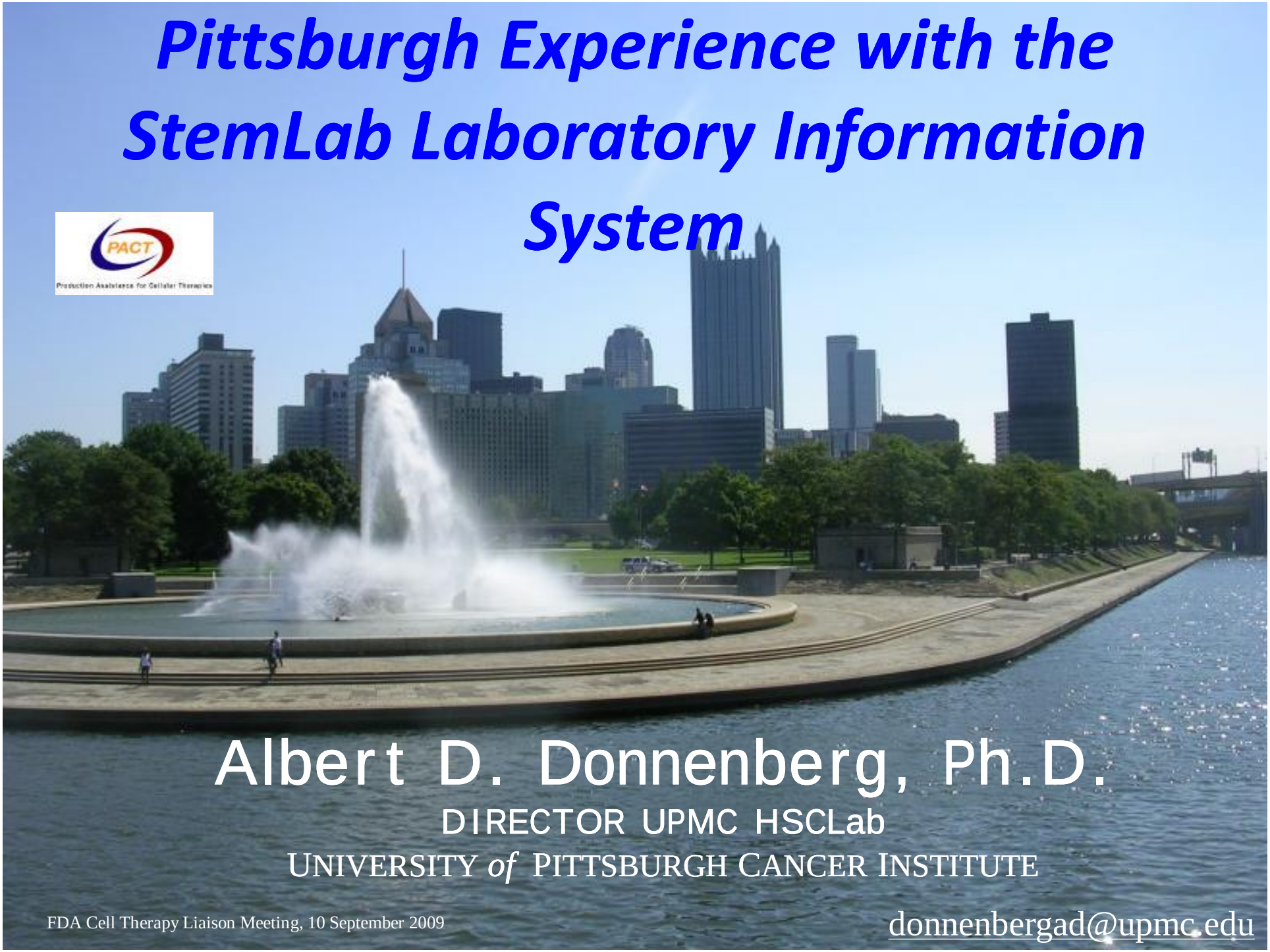
Pittsburgh Experience with the StemLab Laboratory Information System



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STEMSOFT SOFTWARE

STEMLAB & BMTSERVE SYSTEM REQUIREMENTS

SUPPORTED SOFTWARE ENVIRONMENT

SERVER OPERATING SYSTEMS	RELATIONAL DATABASE MANAGEMENT SYSTEMS	CLIENT OPERATING SYSTEMS
• Windows Server 2000, 2003	• Microsoft® SQL Server 2000, 2005 • Oracle® 9i, 10g	• Microsoft® Windows 2000, XP

SERVER HARDWARE RECOMMENDATIONS

CPU	Dual Core Intel® Xeon®, 2.4 GHz (or equivalent)
RAM	4 GB (or higher)
OPERATING SYSTEM	Windows Server® 2003 R2, Standard Edition

CLIENT HARDWARE RECOMMENDATIONS

CPU	Dual Core Intel® 2.0 GHz (or equivalent)
RAM	1 GB (or higher)
OPERATING SYSTEM	Microsoft ® Windows XP SP3

Advertized Features for Quality Product Information

- Record all product sampling and assay results including support for device and HL7 interfaces
  - Manual data input **ü**
  - AcT dif2 hematology instrument **ü**
  - Flow cytometer (not yet)
  - Controlled rate freezer (graphic of freeze curve, not usefull)
  - MET ONE laser particle counter (not yet)
- Enhance quality of data entry with designated fields as 'required' or enforced double entry for validated data fields **ü**
- Document vital data points such as infectious disease screening, sterility, tissue typing, hemoglobinopathy testing, viability, colony-forming units and blood typing (manual entry only, no connection with hospital E-record)
- Standardize processes through protocol driven procedures that track collections, manipulations, segments and products **ü** custom development required for each protocol
- Generate and read ISBT 128 barcode labels along with support for both 1D and 2D barcodes **ü** (not implemented yet)

Advertised Features for Laboratory Operational Information

- Enforce operational sequencing with the ability to include forced data entry pre-requisites, supervisor review status and record lock following final approval **ü**
- Document deviations, complaints and other events and link to a full CAPA (Corrective and Preventive Action) system Events notated but deviations managed on paper
- Access electronic standard operation procedures (SOP's), or link to a full document management system. Capability present, but SOP management manual at present.
- Track all consumable and equipment information and relate each use to individual product manufacturing processes for lot to lot traceability. Was very awkward but problem in software corrected 8/09
- Customize freezer configurations and easily track product and related specimen inventories **ü** works well, some issues with import of legacy data
- Perform ad hoc queries and generate customized reports for outcome analysis and ongoing quality assurance information review. Crystal Reports report generator, calculated parameters are calculated in real time on query. We are dependent on ISD for new queries!

What we had to build

- Create fields for specific tasks(e.g. check cell infusion record) and measurements(e.g dilution factor, empty bag weight).
- Create test batteries (location for test results, e.g. CD34, CBC, ABO Rh)
- Crete processes (e.g. product cyopreservation, thaw, infusion)
- Create protocol-specific process records (protocol flow: accession to cryopreservation or infusion)
- Create protocol-specific decision points (e.g. dilution vs volume reduction)
- Create protocol-specific and queries and reports

What StemSoft built for us:

Custom HL7 interface for hematology instrument, ADT (admissions, discharge transfer), billing module

What limits us from being entirely electronic today?

- System validation (report calculations, operation of system as a whole)
- Development of required reports (cell enumeration, CD34 recovery prediction)
- Data input (cell counts for engraftment)
- Release criteria forms populated from fields in database
- Deviation management
- SOP version management

What else is missing?

- Unable to filter patient demographics (capture records on all local patients, must manually enter patients admitted to affiliated hospitals)
- Generation of data for an external auditor

Worst Fear

- Not independent in ability to rapidly develop and implement new SOPs which require protocol and report builds and new data fields (limited internal resources)