

Pittsburgh Experience with the StemLab Laboratory Information System



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STEMLAB & BMTSERVE SYSTEM REQUIREMENTS

SUPPORTED SOFTWARE ENVIRONMENT

SERVER OPERATING SYSTEMS	RELATIONAL DATABASE MANAGEMENT SYSTEMS	CLIENT OPERATING SYSTEMS
<ul style="list-style-type: none"> Windows Server 2000, 2003 	<ul style="list-style-type: none"> Microsoft® SQL Server 2000, 2005 Oracle® 9i, 10g 	<ul style="list-style-type: none"> 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 ù
 - AcT dif2 hematology instrument ù
 - 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 ù
- 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 ù custom development required for each protocol
- Generate and read ISBT 128 barcode labels along with support for both 1D and 2D barcodes ù (not implemented yet)

Advertised Features for Laboratory Operational Information

- Enforce operational sequencing with the ability to include forced data entry prerequisites, supervisor review status and record lock following final approval ù
- 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 **ù 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)
- Create processes (e.g. product cryopreservation, 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)