CareForum 2022

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Design and Implementation of a Multipurpose Cancer Research Information System based on the NCI-BRIDG Model

CareForum 2022

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Today's speaker

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Professor of Medical Oncology
Division of Hematologic Malignancies and Cellular Therapy
SAS Certified Professional, Version 8
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aka CIDS
Department of Medical Oncology
Thomas Jefferson University School of Medicine

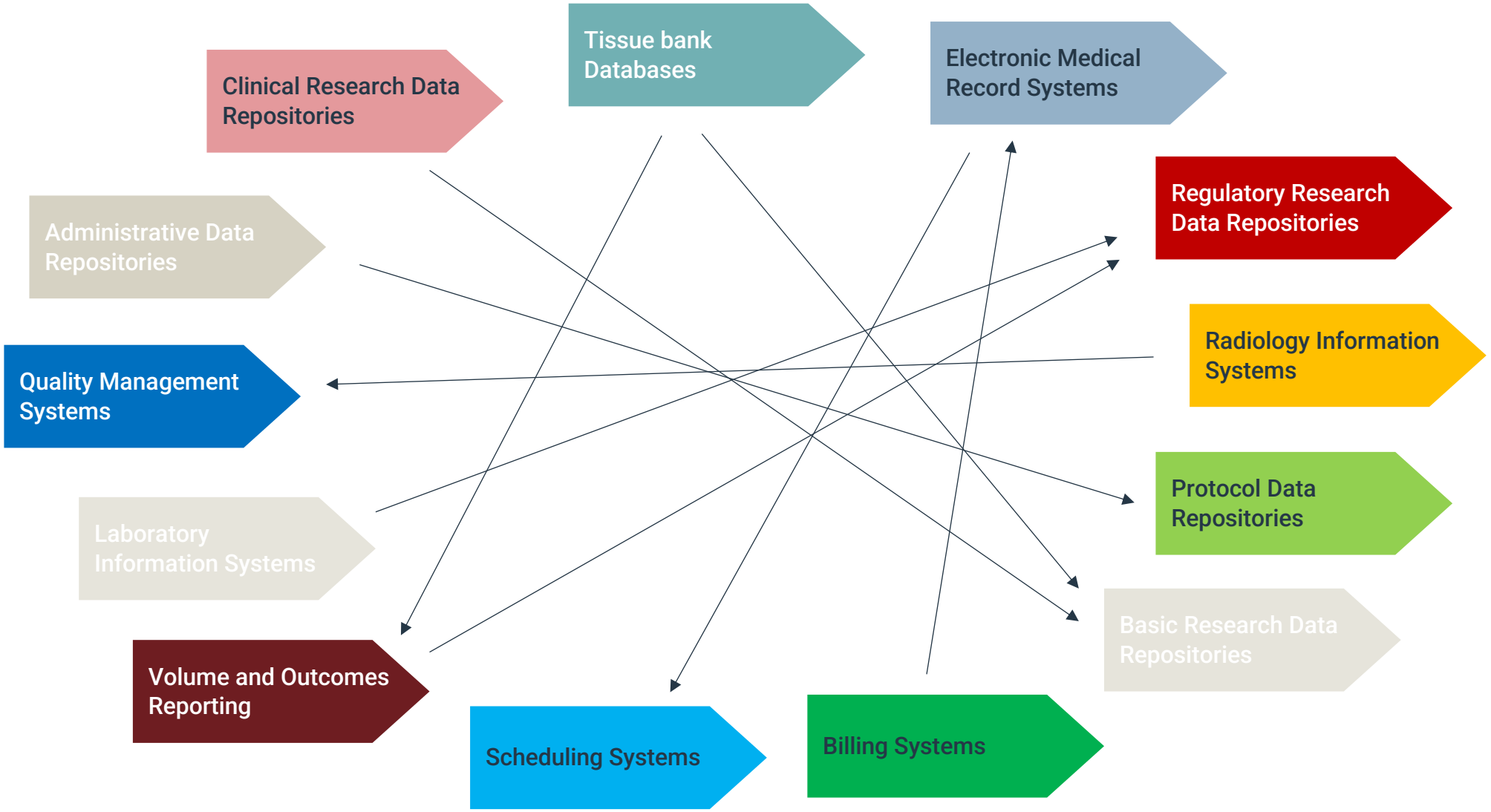
Agenda

- Background and importance
- Design and implementation
- Current functionality
- Summary and future plans

(Plenty of time for comments and questions).

Background and Importance

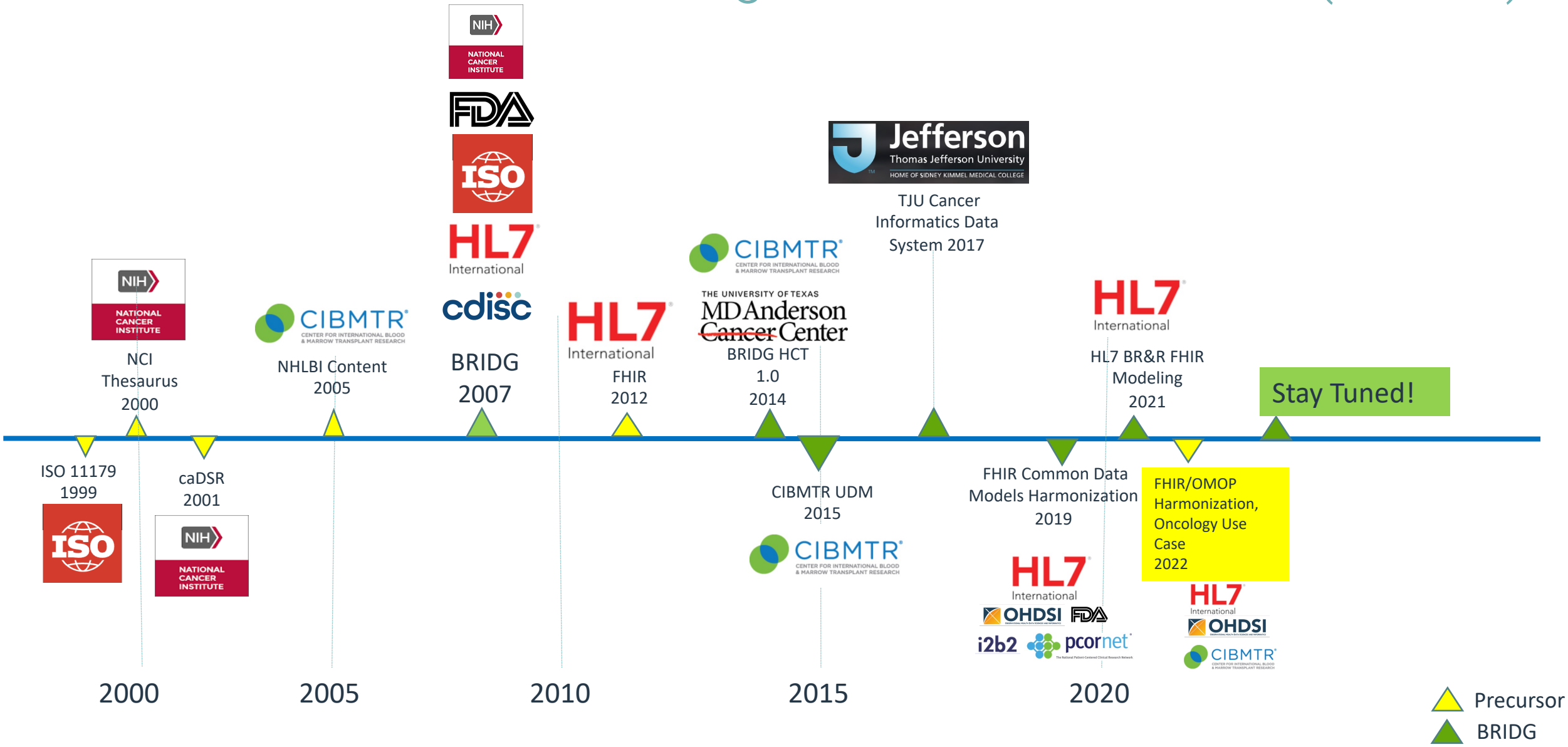
Informatics Infrastructure at a Typical Academic Medical Center



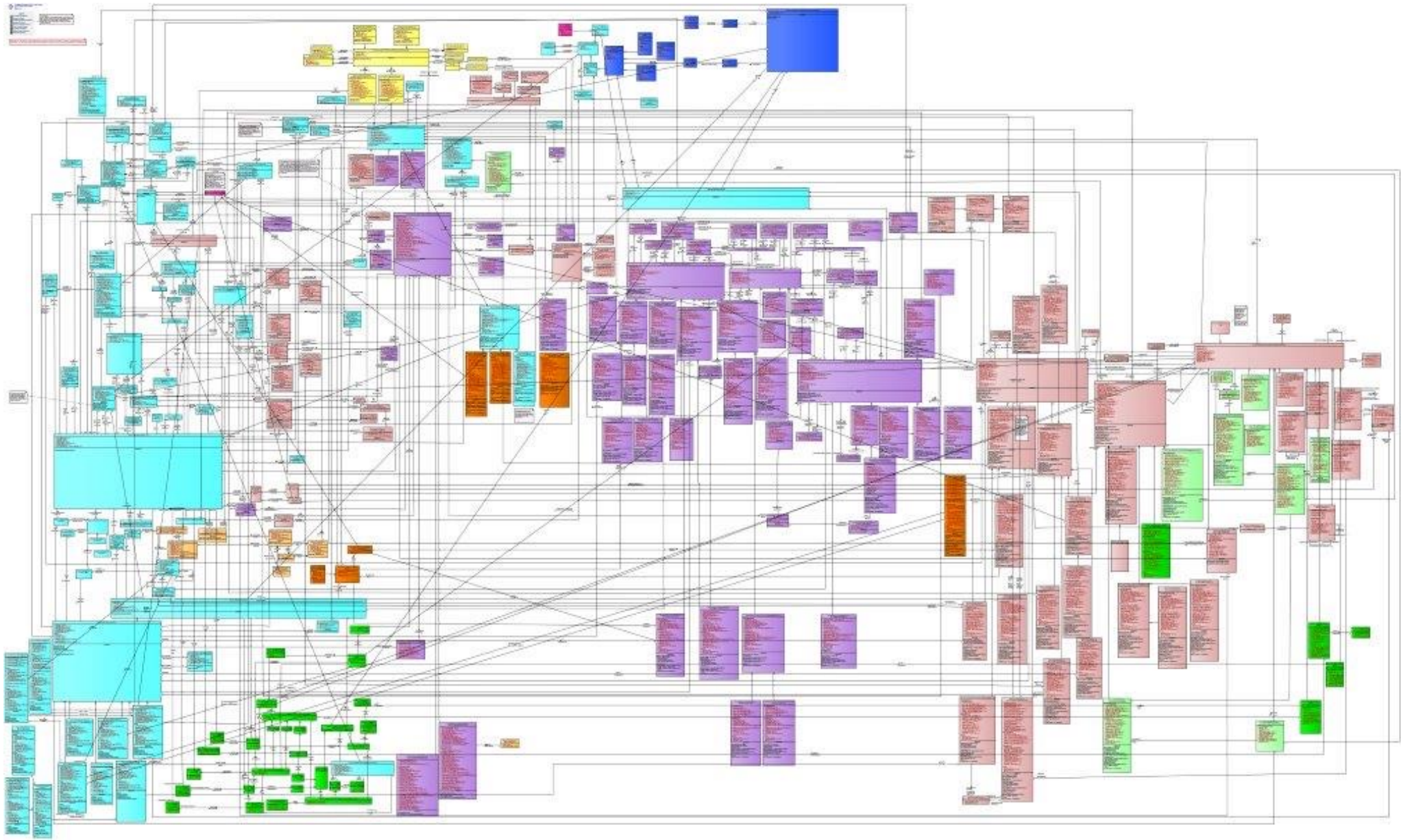
The Chasm of Semantic Despair

- Nearly every data repository is based on a different “data model”
- Attempting to combine or transmit data between repositories based on different data models is a very technically challenging problem
- Combining data that resides in two or more systems that are based on different data models typically requires either extensive manual data extraction or developing complicated software applications called extract, transform, and load (ETL) applications
- Developing these types of ETL applications requires both technical expertise and medical expertise

Biomedical Research Integrated Domain Model (BRIDG)



Overview Diagram of the NCI-BRIDG Model
(The full formal model specification is about 1,000 pages long)



Advantages of The NCI-BRIDG Model

- The BRIDG model “bridges” the multiple chasms of semantic despair that currently exist between data repositories maintained by the following groups of individuals:
  - Basic researchers
  - Translational researchers
  - Clinical researchers
  - Pharmaceutical researchers
  - Governmental research regulators, e.g. NCI, FDA, etc.

Advantages of the NCI-BRIDG Model (2)

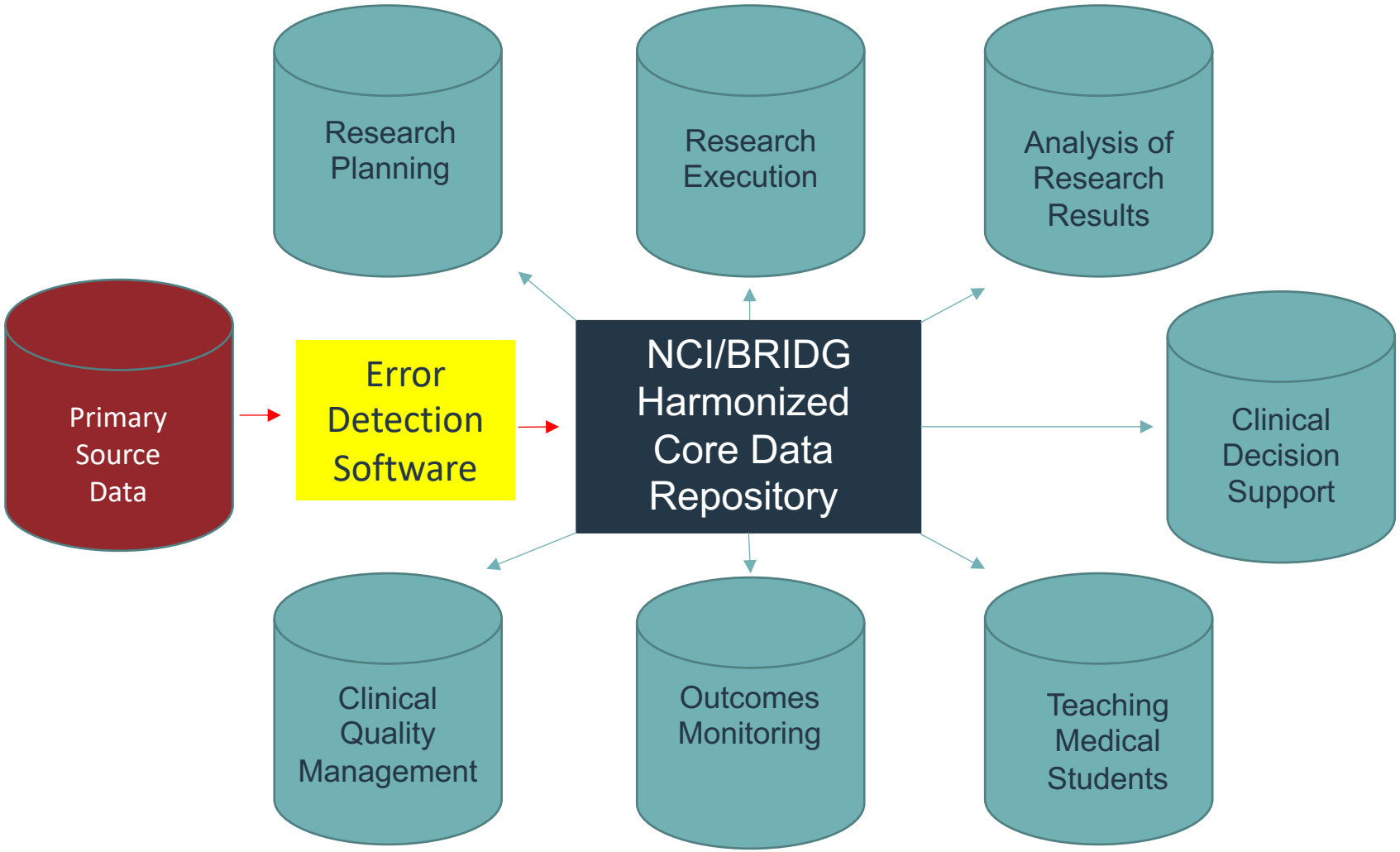
- With relatively minor additional tweaking, we have been able to leverage the BRIDG model to also “bridge” the chasms of semantic despair that currently exist between:
  - Medical researchers
  - Clinicians
  - Patients
  - Medical educators
  - Health care administrators

Disadvantages of the NCI-BRIDG Model

- As shown on an earlier slide, the BRIDG model is extremely complicated, and has therefore been difficult to implement in practice.

Design and Implementation

Cancer Informatics Data System



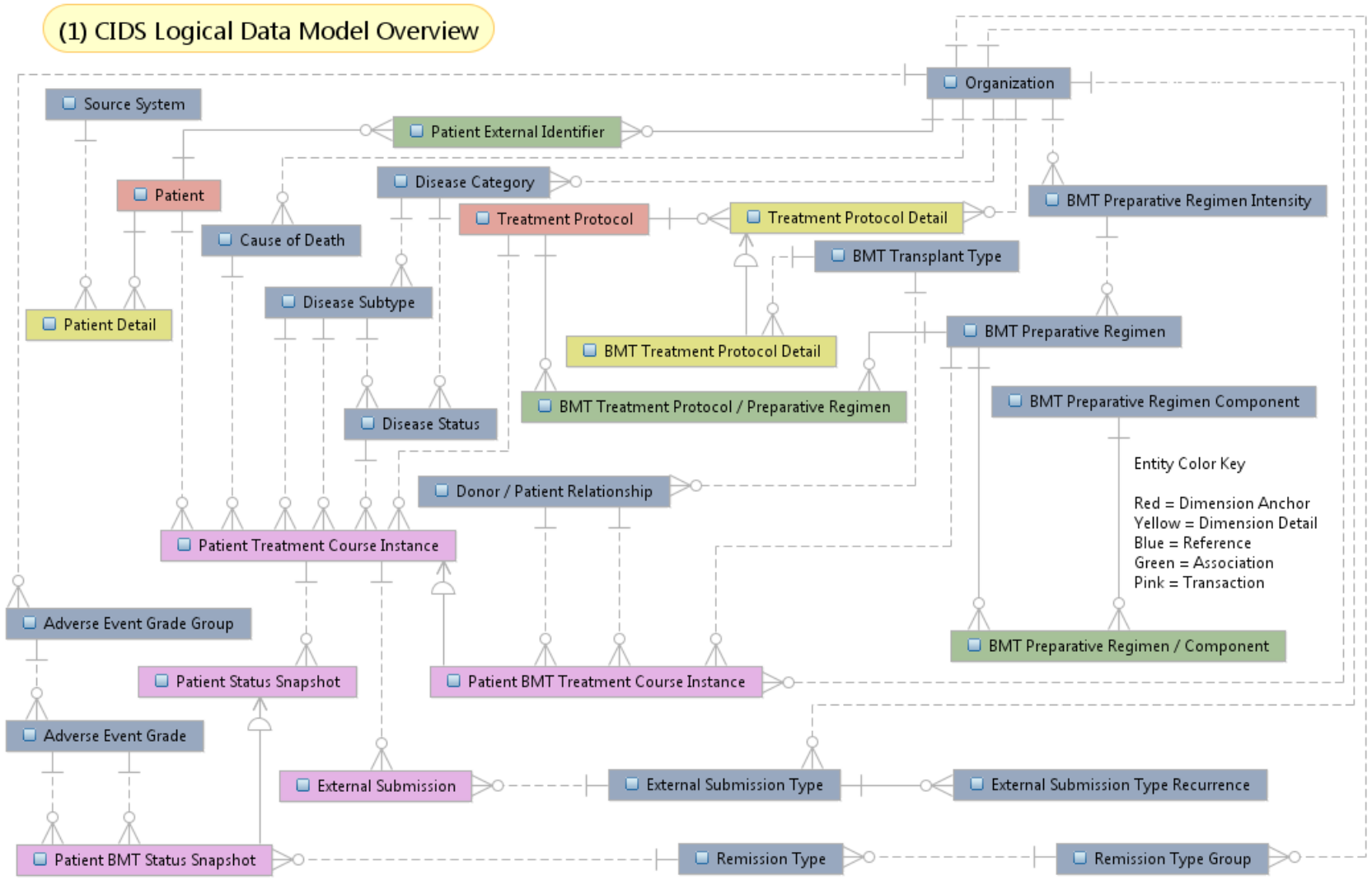
Assemble an Informatics Team

- Primary sponsor
- Secondary sponsors
- Administrative director
- Medical director
- Relational database architects
- Statisticians
- Application developers
- Data managers

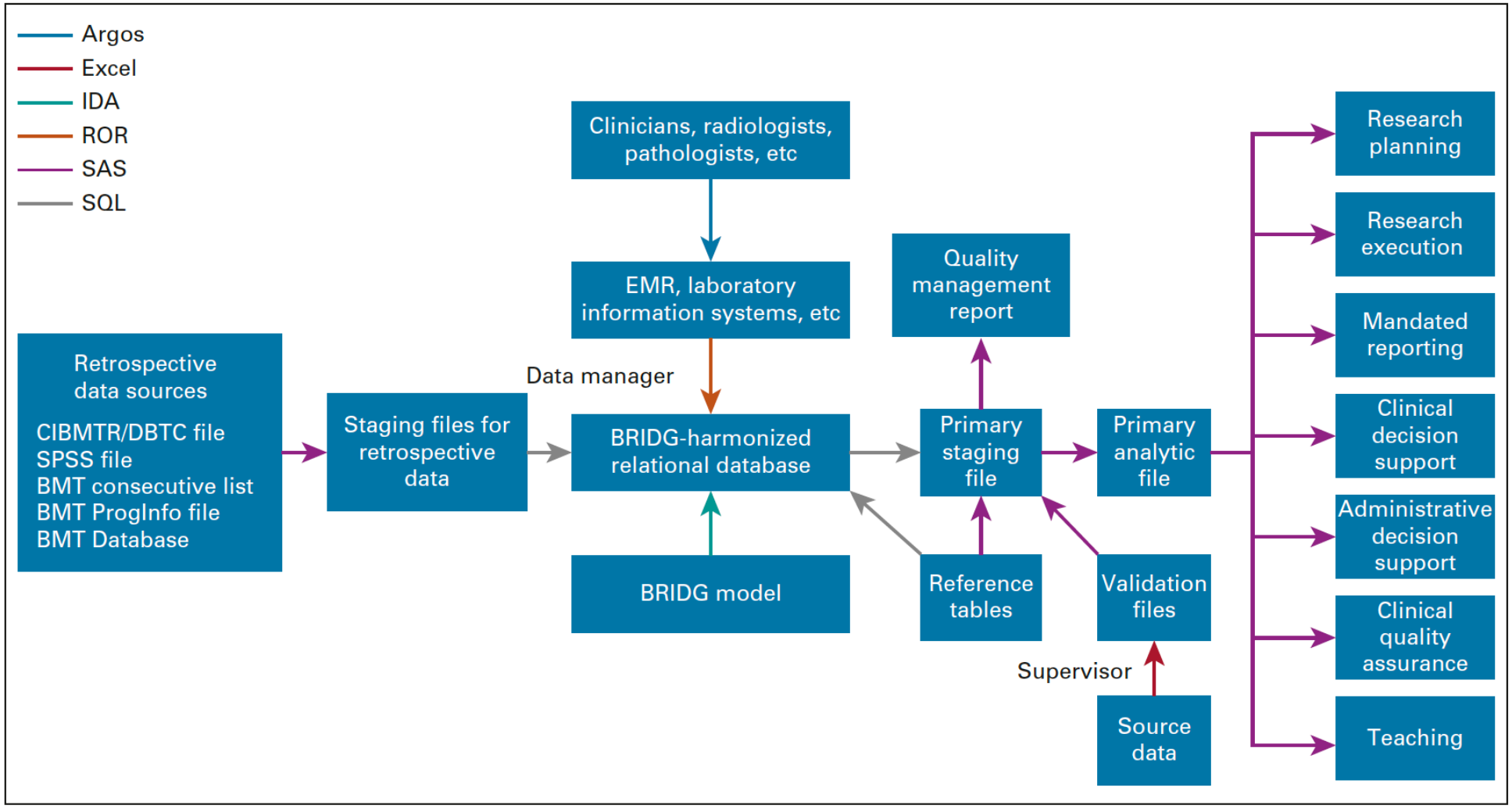
Plan the Development and Implementation Process

- Assign a name to the project: Cancer Informatics Data System (CIDS)
- Divide the project into a series of small steps (iterations)
  - Demonstrate functionality to sponsors early as possible
  - Increase probability of success
- Start with about 50 data elements in the domain of bone marrow transplantation

Develop the CIDS Model

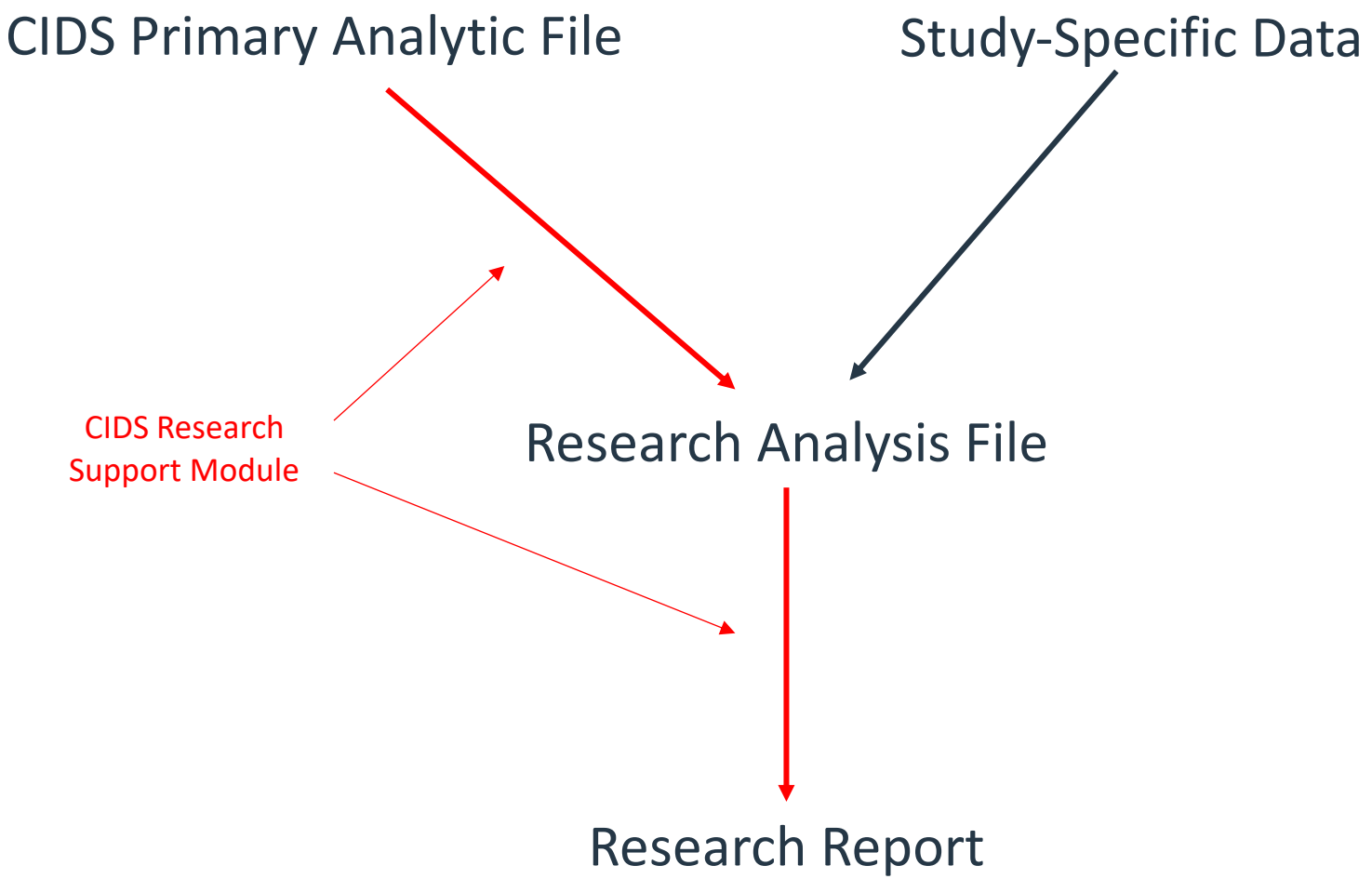


Use the CIDS Model as the Basis for Building the Rest of the System



Current Functionality

Research Support



Research Support

Jefferson
Thomas Jefferson University
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

The Two-Step Haploidentical Allogeneic Stem Cell Transplant Approach Results in Rapid Engraftment and Excellent Outcomes in Patients ≥70 Years Old

Xia Bi, Thomas Klumpp, Usama Gergis, Matthew Carabasi, Joanne Filicko-O'Hara, William O'Hara, John Wagner, Neal Flomenberg, Dolores Grosso
Department of Medical Oncology, Thomas Jefferson University, Philadelphia, PA

INTRODUCTION

Patients ≥70 years old are often excluded from allogeneic hematopoietic stem cell transplantation (allo-HSCT), and there has been a lack of data in this particular population. A novel two-step approach was developed at Thomas Jefferson University that separates the lymphoid and myeloid portions of the graft to avoid the exposure of CD34 cells to cyclophosphamide and to allow a fixed T cell dosing. After conditioning, patients were infused with a fixed dose of 2 x 10^8/kg of donor $CD3^+$ T cells (step 1), followed by cyclophosphamide (CY) for bi-directional T cell tolerization, and finally CD34 selected donor stem

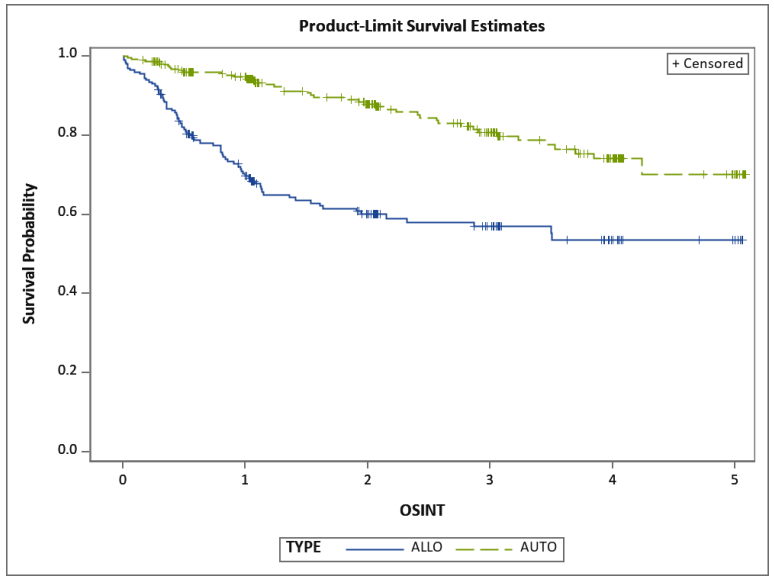
Table 1 Baseline characteristics of patients

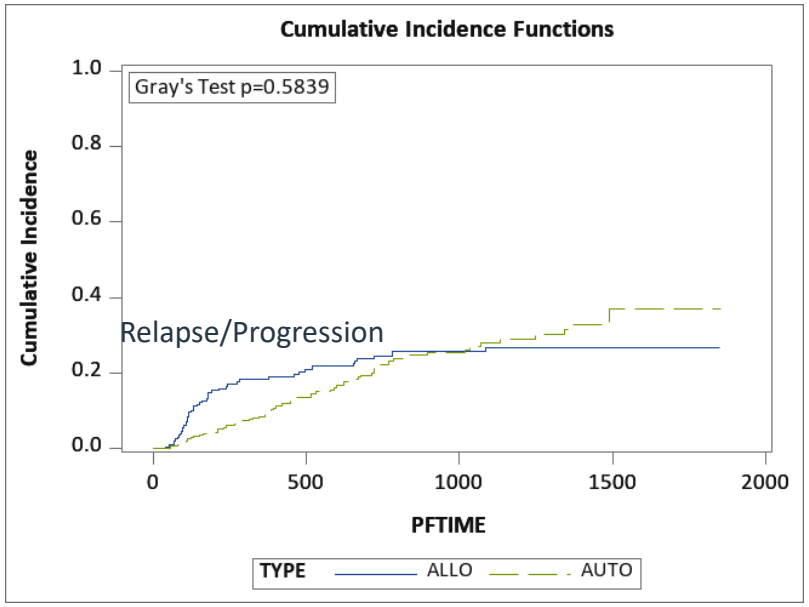
Age	72 (70-76)
Gender (male)	75%
Disease	
AML	5
MDS	5
NHL	2
Disease status prior to Transplant	
CR	8
PR	4
CIBMTR-DRI	
Intermediate	7
High	5
HCT-CI	4 (1-7)
Intensity	
RIC	9
NMA	3

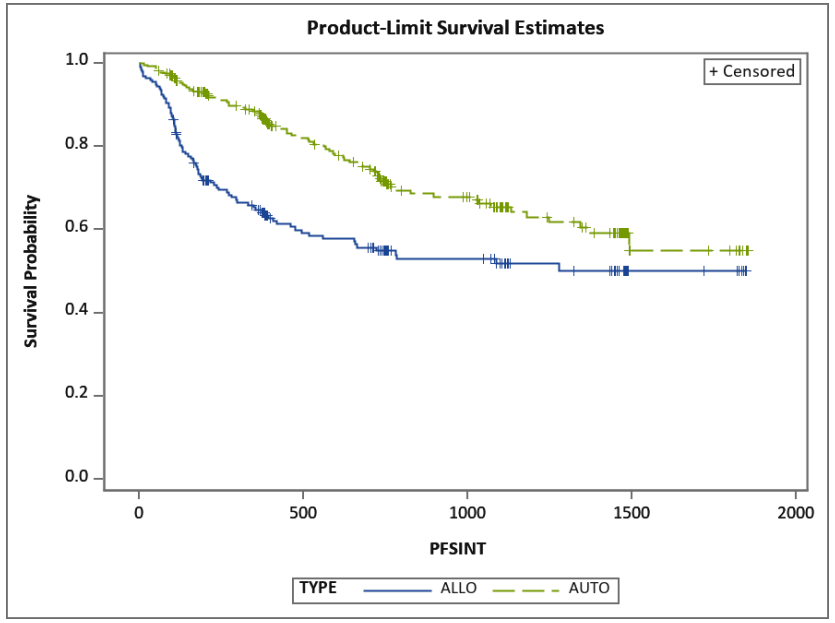
DISCUSSION

Allo-HSCT in the elderly is associated with high treatment-related mortality and risk of relapse, due to medical comorbidities, poor disease biology with underlying treatment resistance, and provider and patient reluctance for such therapy. The two-step approach to allo-HSCT was initially developed in 2005 for patients with HI donors. In our study of patients ≥70 years old, the 3-year overall survival was 45% with a 3-year cumulative incidence of relapse of 17%. This is superior to previously reported overall survival probabilities of approximately 15-45% and relapse rate of 40-60% at 3 years in older patients undergoing

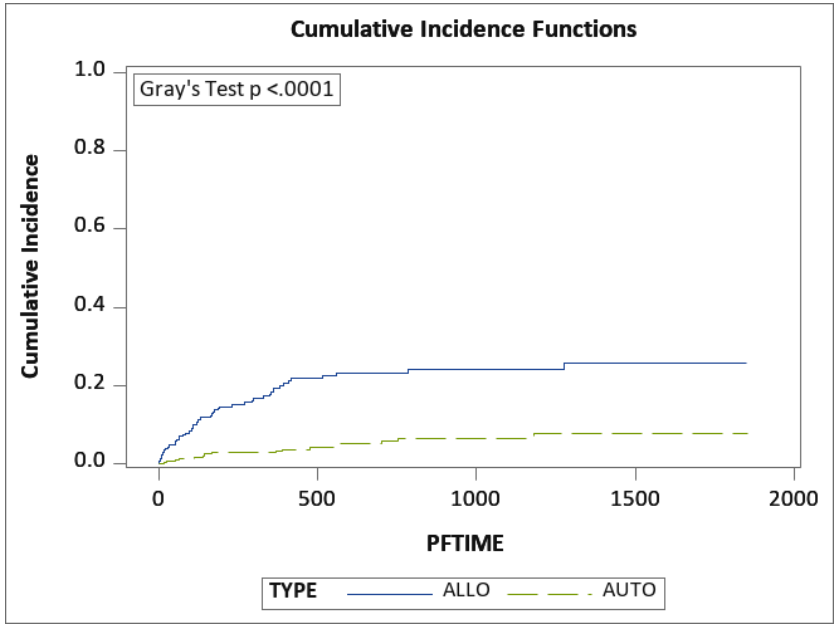
Example: Association Between Donor Type and Outcomes Following Bone Marrow Transplantation







NRM



original reports

DATA ARCHITECTURE AND MODELS

Design and Implementation of a Multipurpose Information System for Hematopoietic Stem-Cell Transplantation on the Basis of the Biomedical Research Integrated Domain Group Model

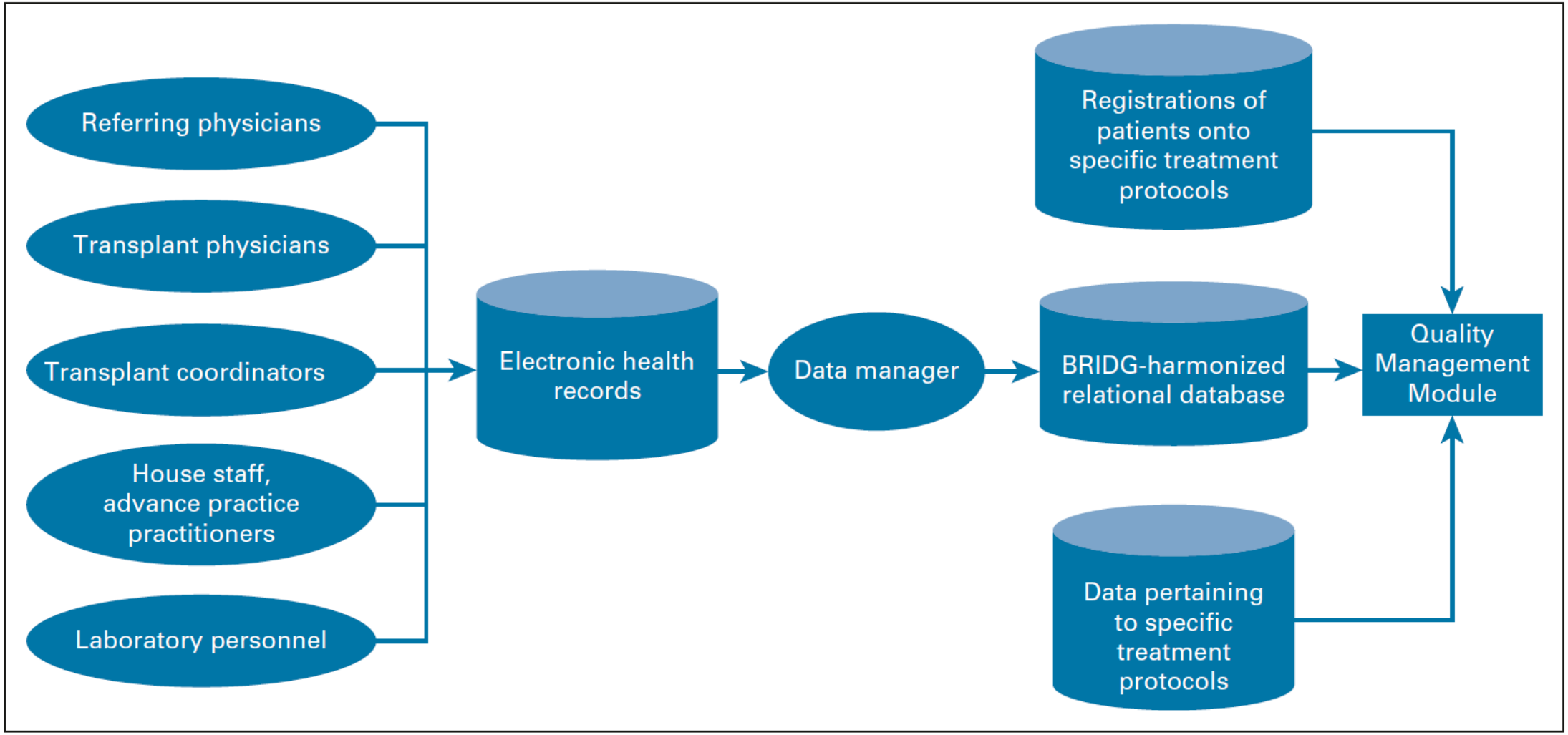
Xia Bi, MD[1]; Dania Beadle, MS[1]; Alexander Xu, BA[2]; Joseph Neff, PhD[3]; Nicholas DeGregorio, PhD[3]; Mouneer Odeh, PhD[4]; Christopher McNair, PhD[5]; Dolores Grosso, DNP[1]; Pierluigi Porcu, MD[1]; Usama Gergis, MD[1]; Neal Flomenberg, MD[1]; and Thomas R. Klumpp, MD[1]

abstract

PURPOSE An important obstacle to cancer research is that nearly all academic cancer centers maintain substantial collections of highly duplicative, poorly quality-assured, nonintercommunicating, difficult-to-access data repositories. It is inherently clear that this state of affairs increases costs and reduces quality and productivity of both research and nonresearch activities. We hypothesized that designing and implementing a multipurpose cancer information system on the basis of the Biomedical Research Integrated Domain (BRIDG) model developed by the National Cancer Institute and its collaborators might lessen the duplication of effort inherent in capturing, quality-assuring, and accessing data located in multiple single-purpose systems, and thereby increases productivity while reducing costs.

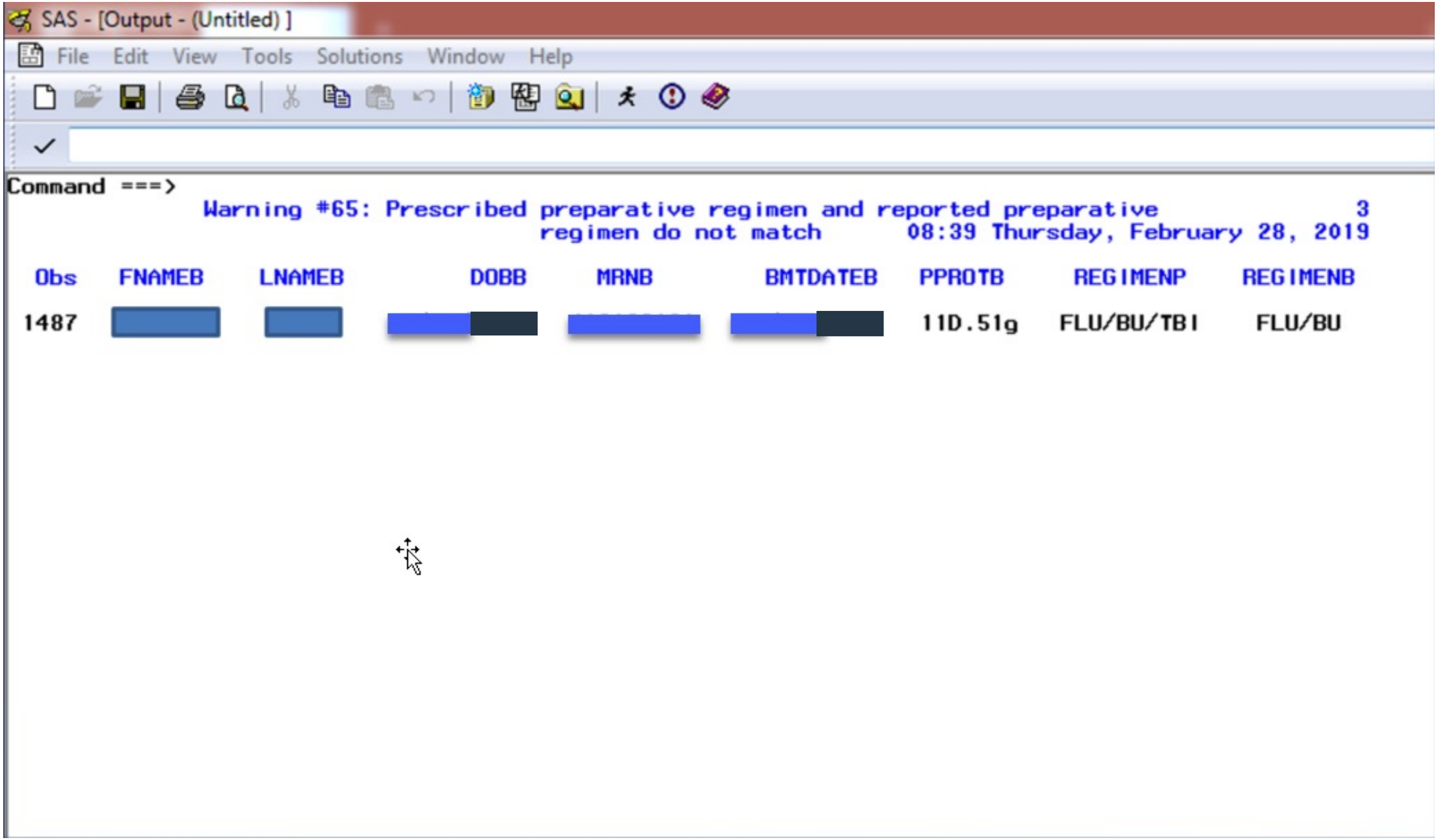
METHODS We designed and implemented a core data structure on the basis of the BRIDG model and incorporated multiple entities, attributes, and functionalities to support the multipurpose functionality of the

CIDS Quality Management Functionality



CIDS Quality Management Module

- The CIDS Quality Management Module continually compares what is supposed to be happening to each patient, based on the treatment protocol or protocols according to which the patient is being treated, against what is reported to be happening to each patient based on the information abstracted from the electronic medical records systems
- This feature is made possible by the NCI/BRIDG data model itself, which explicitly resolves the many-to-many relationship between patients and treatment protocols


SAS - [Output - (Untitled)]
File Edit View Tools Solutions Window Help
Command ===>
Warning #65: Prescribed preparative regimen and reported preparative regimen do not match
3
08:39 Thursday, February 28, 2019
Obs FNAMEB LNAMEB DOBB MRNB BMTDATEB PPROTB REGIMENP REGIMENB
1487 11D.51g FLU/BU/TBI FLU/BU

Patient Safety

Medications

Report

Scheduled

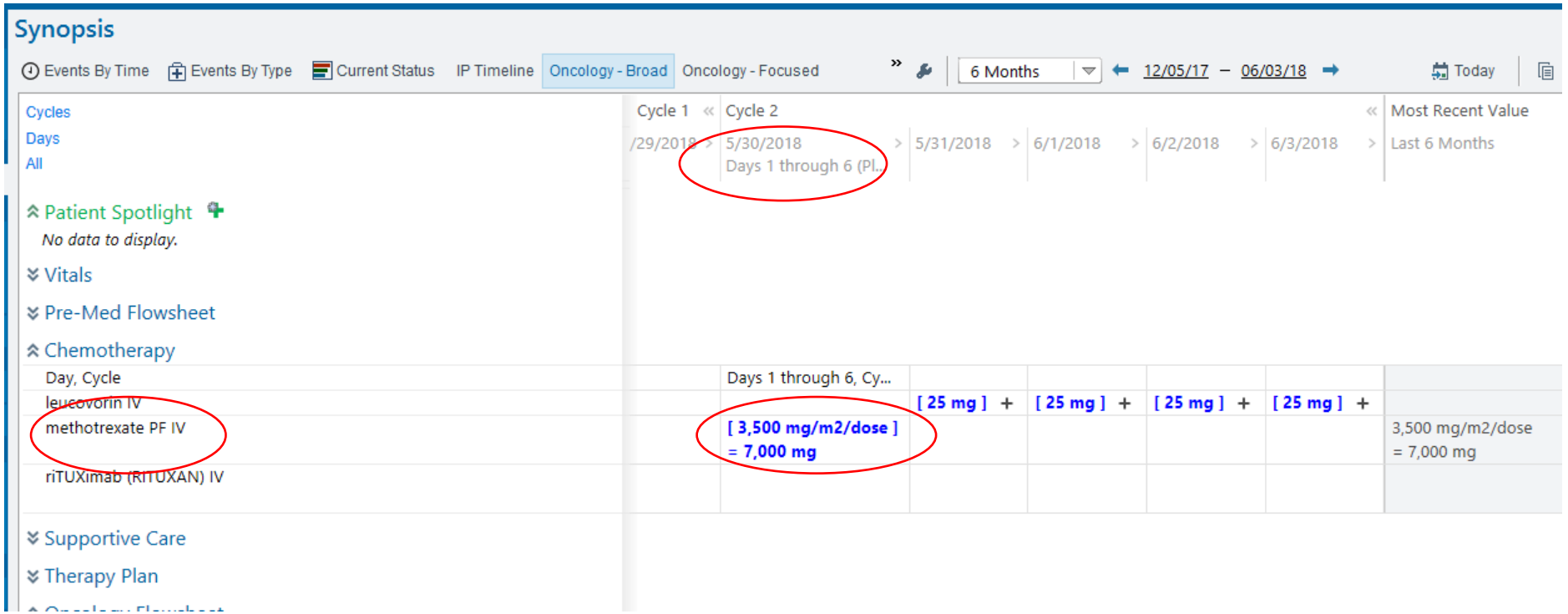
Medication	Dose/Rate, Route, Frequency	Last Action
acyclovir (ZOVIRAX) tablet 800 mg	800 mg, oral, Q12H SCH	Given: 04/13 0828
allopurinol (ZYLOPRIM) tablet 300 mg	300 mg, oral, Daily	Given: 04/13 0828
arsenic trioxide (TRISENOX) 12.4 mg in dextrose 5 % 100 mL chemo IVPB	0 mg, IV, Q24H	Stopped: 04/12 1805
fluconazole (DIFLUCAN) tablet 400 mg	400 mg, oral, Daily	Given: 04/13 0828
insulin lispro (HumaLOG) injection 1-5 Units	1 Units, subQ, CDI with meals	Given: 04/10 1714
insulin lispro (HumaLOG) injection 2-3 Units	2-3 Units, subQ, CDI PM	Ordered
levothyroxine (SYNTHROID, LEVOTHROID) tablet 25 mcg	25 mcg, oral, Q0600	Given: 04/13 0548
prochlorperazine (COMPAZINE) 10 mg in sodium chloride 0.9 % 100 mL IVPB	0 mg, IV, Q24H	Stopped: 04/12 1655
sodium chloride 0.9 % flush 10 mL	10 mL, IV, Q12H SCH	Ordered
sodium chloride 0.9 % flush 3 mL	3 mL, IV, Q8H SCH	Ordered
tretinoin (VESANOID) chemo capsule 40 mg	40 mg, oral, Q12H	Given: 04/13 0958

PRN

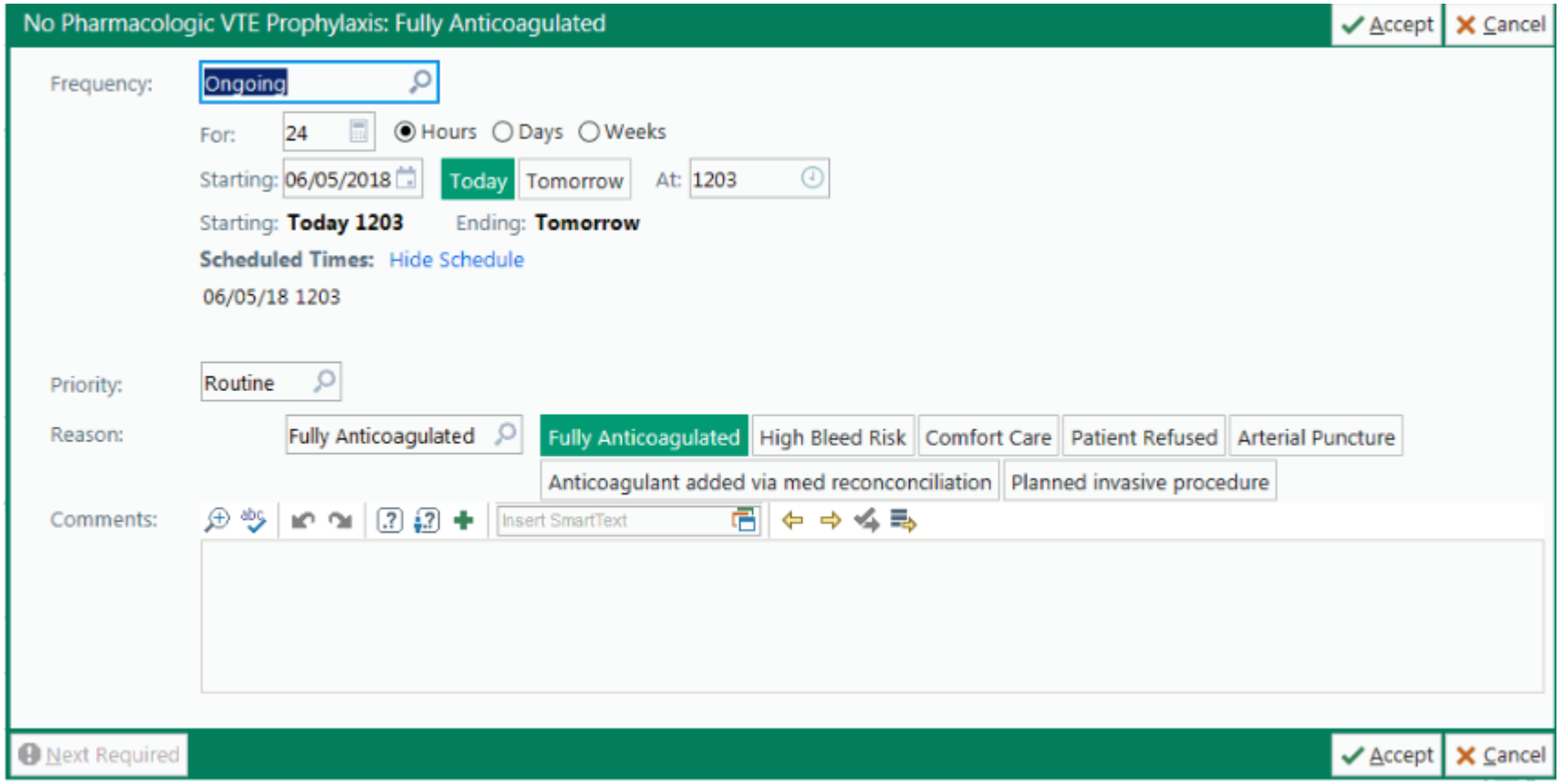
Patient Safety

(ONCOVIN) 0.88 mg in sodium chloride 0.9 % 1,000 mL chemo IVPB Freq: Every 24 hours Route: IV Last Dose: Stopped (03/11/18 1501) Start: 03/07/18 1430 End: 03/11/18 1501 › Admin Instructions:										
DOXOrubicin (ADRIAMYCIN) 32 mg, etoposide (TOPOSAR) 160 mg, vinCRIStine (ONCOVIN) 0.88 mg in sodium chloride 0.9 % 1,000 mL chemo IVPB Freq: Every 24 hours Route: IV Last Dose: Stopped (04/22/18 1217) Start: 04/18/18 1415 End: 04/22/18 1217 › Admin Instructions:										
DOXOrubicin (ADRIAMYCIN) 38 mg, etoposide (TOPOSAR) 190 mg, vinCRIStine (ONCOVIN) 0.88 mg in sodium chloride 0.9 % 1,000 mL chemo IVPB Freq: Every 24 hours Route: IV Start: 05/30/18 1500 End: 06/03/18 1459 › Admin Instructions:						1503	1424	1342 [C]	1314 [C] ~~1500 [C]~~	1459-D/C'd
DOXOrubicin (ADRIAMYCIN) 38 mg, etoposide (TOPOSAR) 190 mg, vinCRIStine (ONCOVIN) 0.88 mg in sodium chloride 0.9 % 1,000 mL chemo IVPB Freq: Every 24 hours Route: IV Last Dose: Stopped (05/13/18 1640) Start: 05/09/18 1600 End: 05/13/18 1640 › Admin Instructions:										
enoxaparin (LOVENOX) syringe 40 mg Dose: 40 mg Freq: Every 24 hours Route: subQ Start: 05/30/18 1145						1206	1127	1128	1109	1145
enoxaparin (LOVENOX) syringe 40 mg Dose: 40 mg Freq: Every 24 hours Route: subQ Start: 05/09/18 1145 End: 05/13/18 2038										
enoxaparin (LOVENOX) syringe 40 mg Dose: 40 mg Freq: Every 24 hours Route: subQ Start: 04/18/18 1230 End: 04/22/18 1739										

Patient Safety



Patient Safety



Patient Safety

Subjective

Objective

Assessment/Plan

Assessment/Plan

1. Multiple myeloma in remission (CMS/HCC) (Primary)

Overview:

Bone marrow biopsy: Myeloma. Stage 3.
No M spike in serum, IgG kappa on IF. Cr 2.2, Hgb 9, Albumin 3.3, Beta 2 micro 6.9, Kappa LC in urine 121mg/dl.
Complex Karyotype with high risk features.

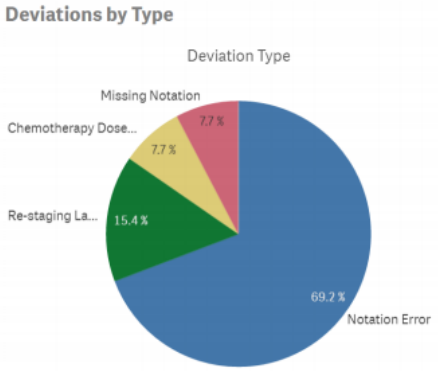
2. Papular rash, localized

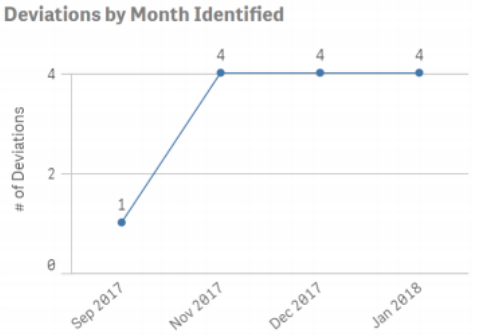
It appears that myeloma is in remission. She will start Xgeva today. The cause of the rash remains uncertain but does not appear clearly related to Revlimid as initially thought since it has not cleared up with her being off the Revlimid now for 3 weeks. I suggested dermatology evaluation with Dr. Kligman and we can then decide how to proceed with maintenance treatment after she is evaluated there.

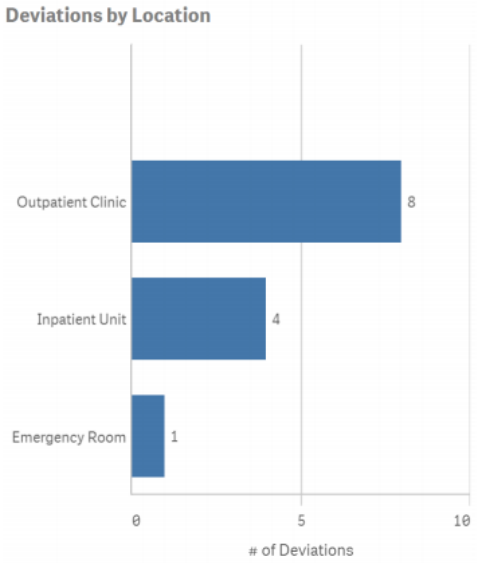
Patient Safety

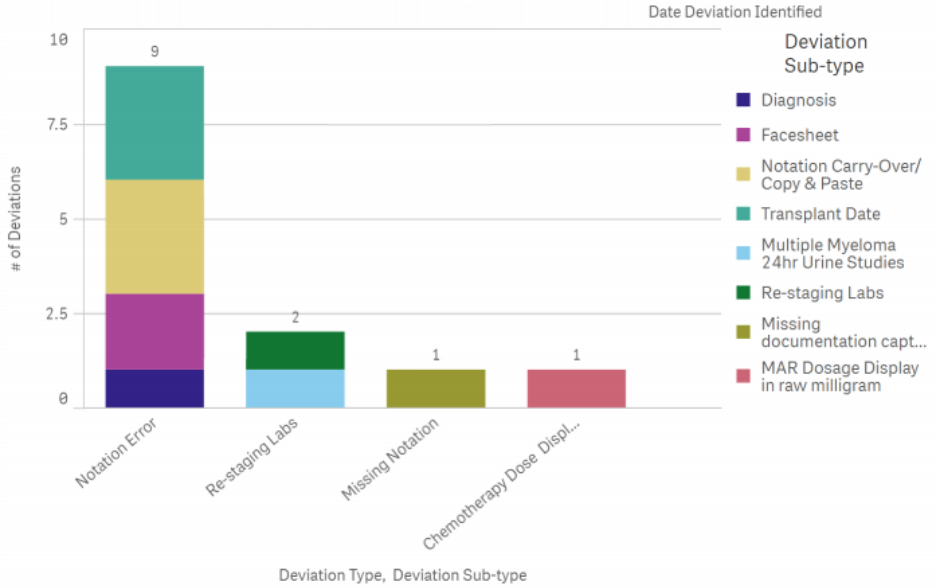
Deviations Identified To Date

175



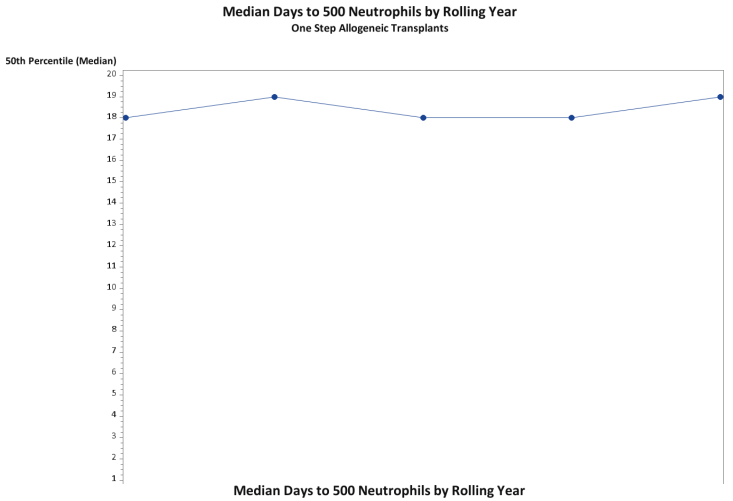


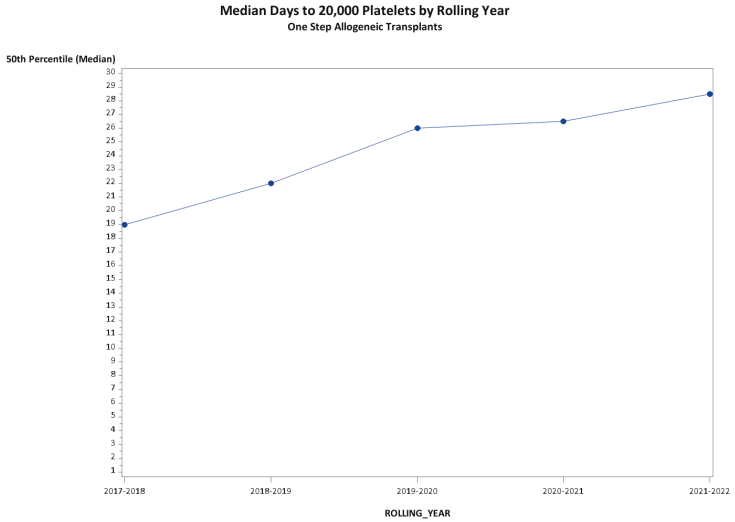


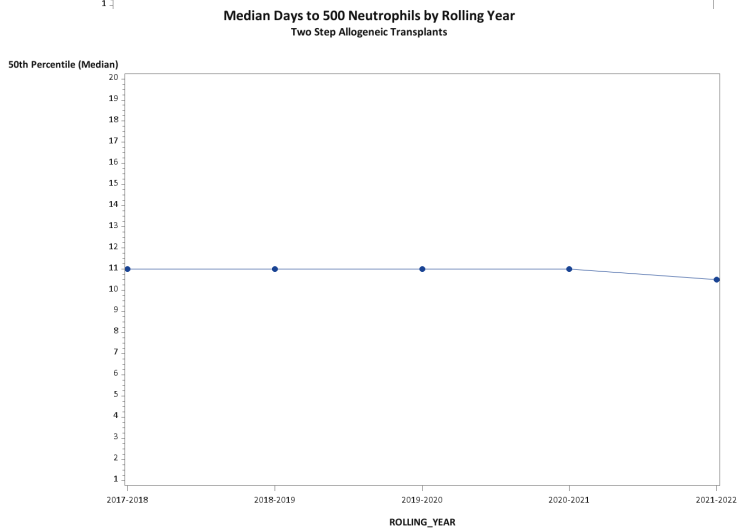


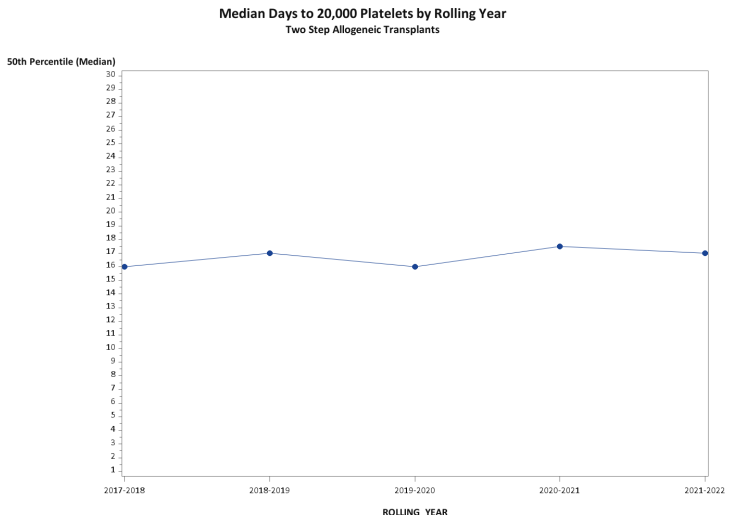
Clinical Decision Support

- Example: Median rate of blood count recovery following various categories of bone marrow transplant





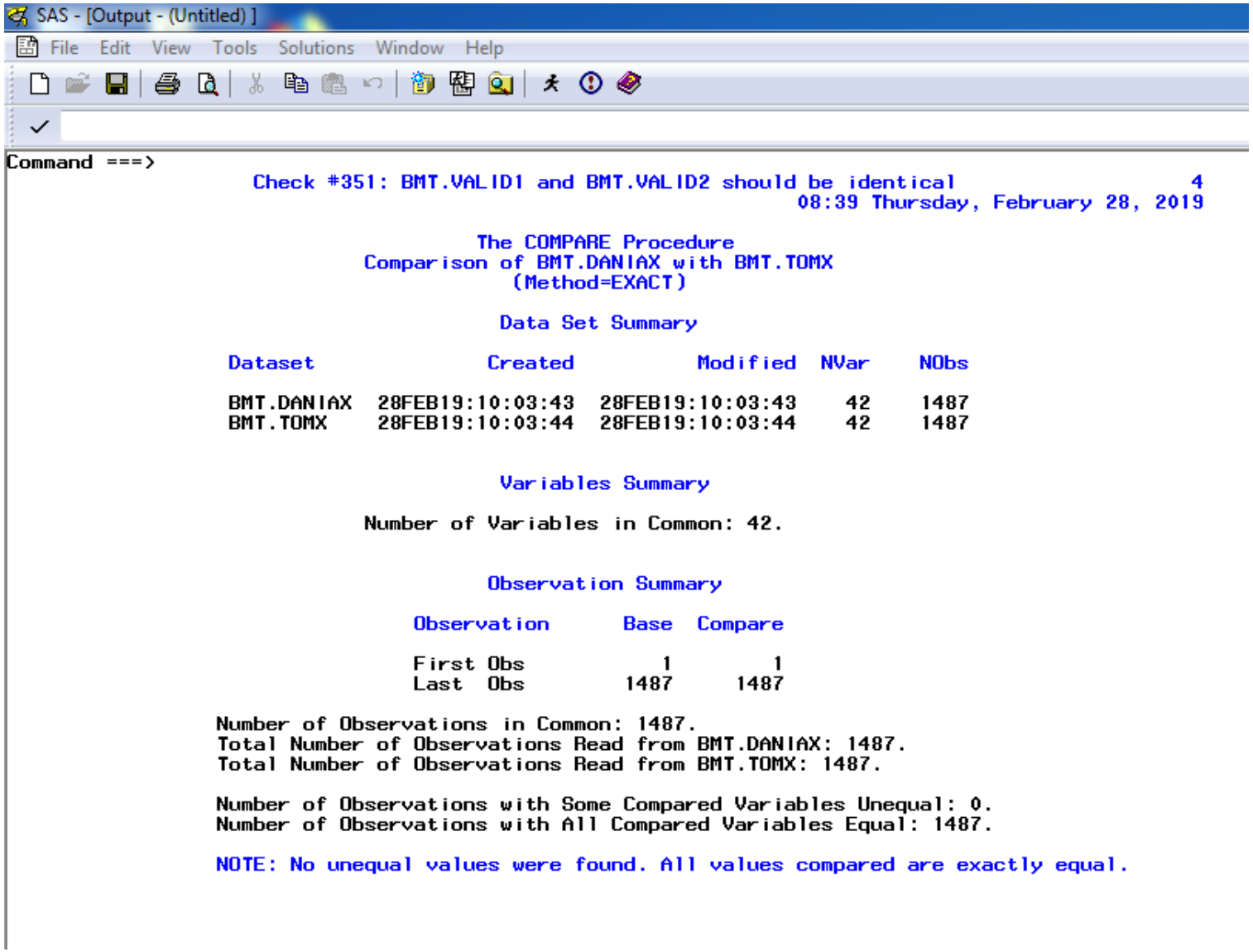




Research Integrity and Productivity

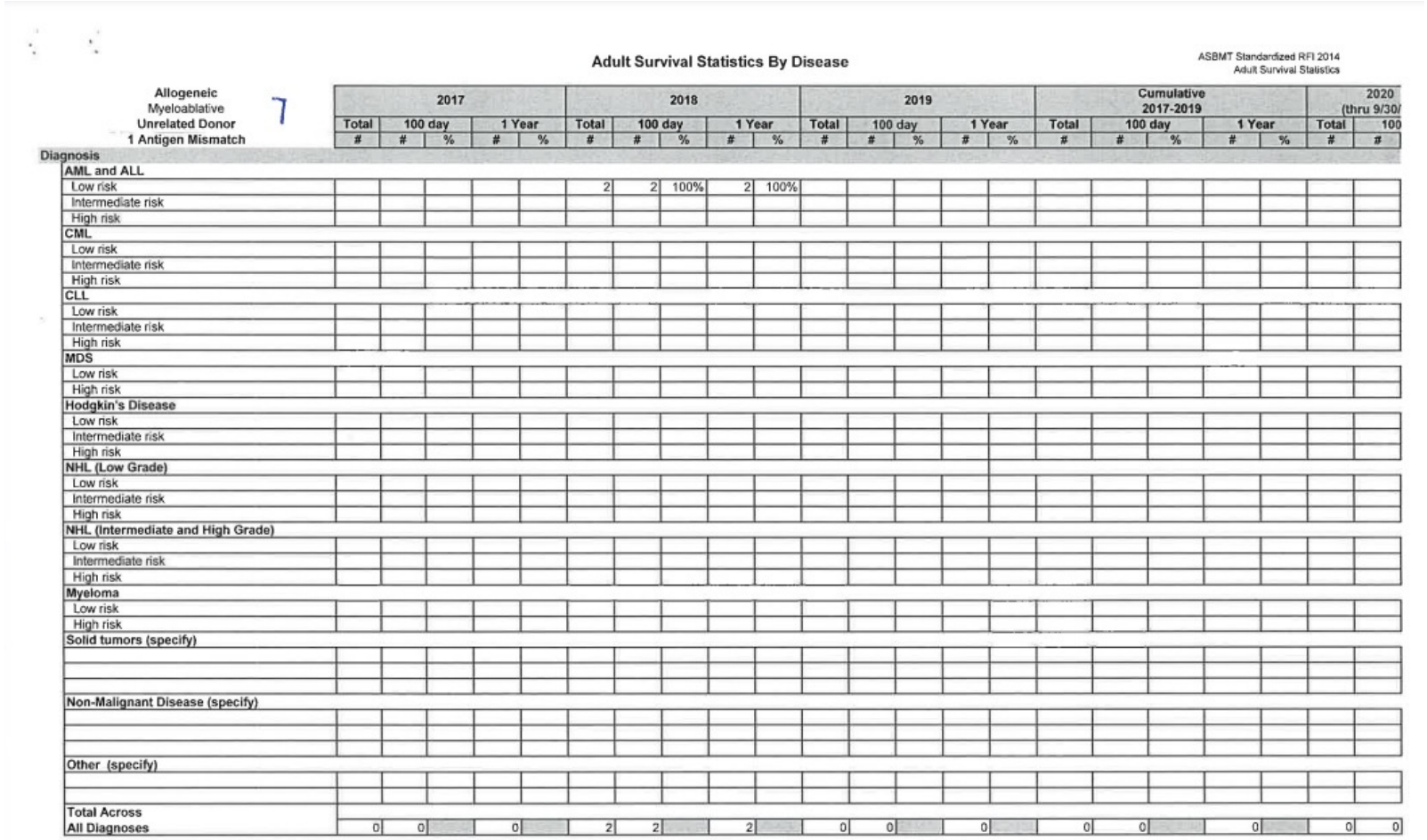
- Detected and corrected 73 errors among the first 886 data values examined in our existing research data repository
- Reduced prevalence or erroneous data from about 8% to < 1%
- Reduces risk of obtaining false-positive or false-negative research results
- Carrying out electronic data transfers to our existing research data repository
- Beginning the process of folding our existing research data repository into our new core information system

Training New Data Managers




```
                    Check #351: BMT.VALID1 and BMT.VALID2 should be identical                4
                                                                  08:39 Thursday, February 28, 2019

                                        The COMPARE Procedure
                                    Comparison of BMT.DANIAX with BMT.TOMX
                                              (Method=EXACT)

                                          Data Set Summary

                  Dataset                Created             Modified   NVar     NObs

                  BMT.DANIAX   28FEB19:10:03:43   28FEB19:10:03:43     42     1487
                  BMT.TOMX     28FEB19:10:03:44   28FEB19:10:03:44     42     1487


                                        Variables Summary

                                Number of Variables in Common: 42.


                                       Observation Summary

                                    Observation      Base  Compare

                                    First Obs           1        1
                                    Last  Obs        1487     1487

                  Number of Observations in Common: 1487.
                  Total Number of Observations Read from BMT.DANIAX: 1487.
                  Total Number of Observations Read from BMT.TOMX: 1487.

                  Number of Observations with Some Compared Variables Unequal: 0.
                  Number of Observations with All Compared Variables Equal: 1487.

                  NOTE: No unequal values were found. All values compared are exactly equal.
```

Mandated Reporting to Outside Regulatory and Accreditation, Certification, and Regulatory Bodies



Adult Survival Statistics By Disease

ASBMT Standardized RFI 2014
Adult Survival Statistics

Allogeneic Myeloablative Unrelated Donor 1 Antigen Mismatch	2017					2018					2019					Cumulative 2017-2019					2020 (thru 9/30/	
	Total	100 day		1 Year		Total	100 day		1 Year		Total	100 day		1 Year		Total	100 day		1 Year		Total	100
	#	#	%	#	%	#	#	%	#	%	#	#	%	#	%	#	#	%	#	%	#	#
Diagnosis																						
AML and ALL																						
Low risk						2	2	100%	2	100%												
Intermediate risk																						
High risk																						
CML																						
Low risk																						
Intermediate risk																						
High risk																						
CLL																						
Low risk																						
Intermediate risk																						
High risk																						
MDS																						
Low risk																						
High risk																						
Hodgkin's Disease																						
Low risk																						
Intermediate risk																						
High risk																						
NHL (Low Grade)																						
Low risk																						
Intermediate risk																						
High risk																						
NHL (Intermediate and High Grade)																						
Low risk																						
Intermediate risk																						
High risk																						
Myeloma																						
Low risk																						
High risk																						
Solid tumors (specify)																						
Non-Malignant Disease (specify)																						
Other (specify)																						
Total Across All Diagnoses	0	0		0		2	2		2		0	0		0		0	0		0		0	0

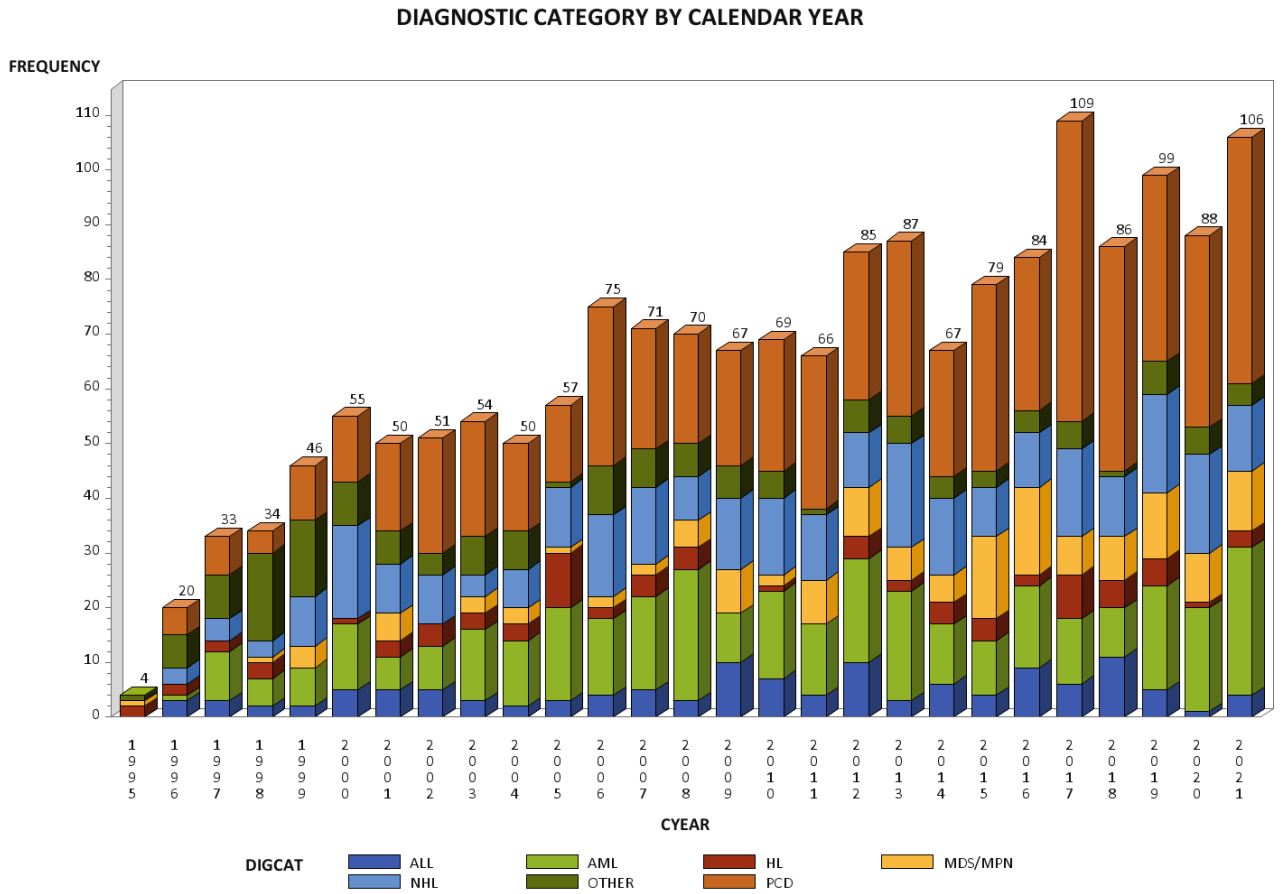
Transplant Program Name:

7 of 24

Copyright 2014, ASBMT

Administrative Decision Support

- Generate analysis to support various administrative decisions
- Example: What is the annual trend in the number and types of transplants performed?



Other Types of Support

- Cell Processing support
- Teaching medical students, interns, residents, and fellows

Summary and Future plans

Summary

- The Cancer Informatics Team at Thomas Jefferson has been able to leverage the NCI-BRIDG model to implement a multipurpose cancer research information system that increases research productivity, enhances patient safety, and supports a wide variety of patient care, teaching, research, and administrative activities

Future Plans

- Migrate the data and functionality from CIDS into the WellSky Biotherapies Clinic
- Migrate the additional data and functionality that resides in our single-purpose repositories into Biotherapies Clinic
- Over time this process will enable us to significantly reduce costs by discontinuing support for our large collection of single-purpose repositories

CareForum 2022

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Questions?

Contact us:

Contact name: Thomas R. Klumpp, MD

Contact title: Professor of Medical Oncology

Email address: Thomas.Klumpp@Jefferson.edu

Learn more about WellSky Biotherapies

Request a consultation today!

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