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CER, EHRs and the Elekta Radiation Oncology Data Alliance

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*Human Care Makes
the Future Possible*

Agenda

- Elekta and Elekta Software

- Cancer, Radiation Oncology and CER

- Radiation Oncology Data Alliance (RODA) Program Overview

- Program Status/Challenges

- Questions

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About Elekta, Inc.

- Est. 1972. World leader in image guided / clinical solutions for radiosurgery and radiation therapy
- Manufactures advanced technological solutions
- Provides healthcare IT solutions (Impac Software) that streamline clinical and business operations across the spectrum of cancer care including Medical and Radiation Oncology
- Has > 1,200 RO and MO USA EHR customers
- Has established two EHR-derived registry programs (MO and RO)

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What is Radiation Oncology / Radiation Therapy?

- Treatment of Cancer using ionizing radiation

- Used in approx 2/3 of 1.4M cancer patients diagnosed per year and 10M surviving cancer patients

- Most common cancers treated: Lung, Breast, Prostate, Colorectal

    - Treatment typically utilizes very high technology: linear accelerator (photons), protons, radioactive isotopes...

- Consumes approx. $8B of $80B direct US cancer treatment expenses per year

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Cancer as a Comparative Effectiveness Research Priority

- **Cancer focus of 6 primary topics including:**

  - **Hematology/Oncology**

  - **Use of screening technologies for colorectal and breast cancer**

  - **Use of imaging technologies for cancer diagnosis, staging and monitoring**

- *"Emphasis on exploring increased use of advanced imaging reflects concern that has already led Congress to take steps to reduce the rapid growth in the use of such tests under Medicare; private insurers have made similar efforts to control imaging use."*
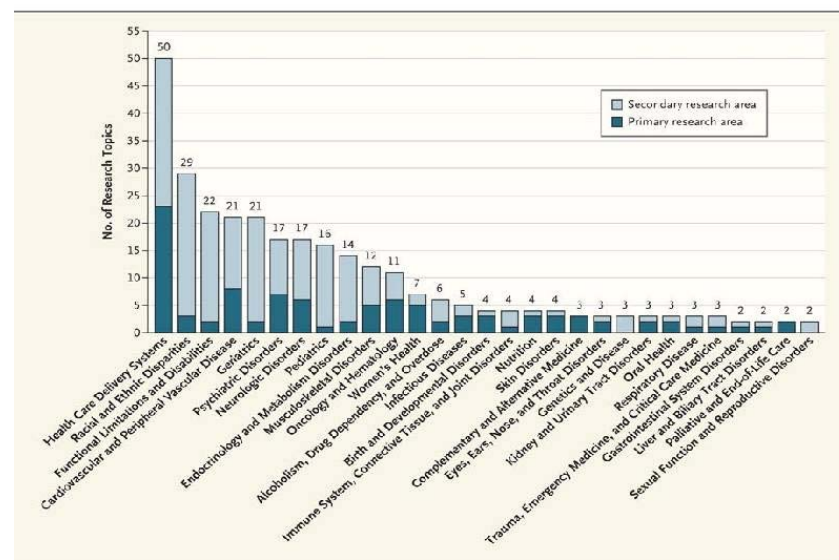
Distribution of the IOM's Recommended CER Priorities

Radiation Oncology and CER

- High technology

- Imaging-dependent

- Regulatory: 510k clearance unlike pharma approval
  - *e.g. - [Linear Accelerator] Intended use for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed medical practitioner*

- Protracted time to provide supporting clinical evidence
  - Technology typically available well before evidence
  - Significant trade-offs often between efficacy, toxicity, convenience and costs
  - Example: Prostate Cancer

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Prostate Cancer: Prime for CER

- Wide range of treatment costs
- Arguable trade offs between efficacy, morbidity and time/convenience
- Advanced imaging required for diagnosis and treatment
- CER: On its way?

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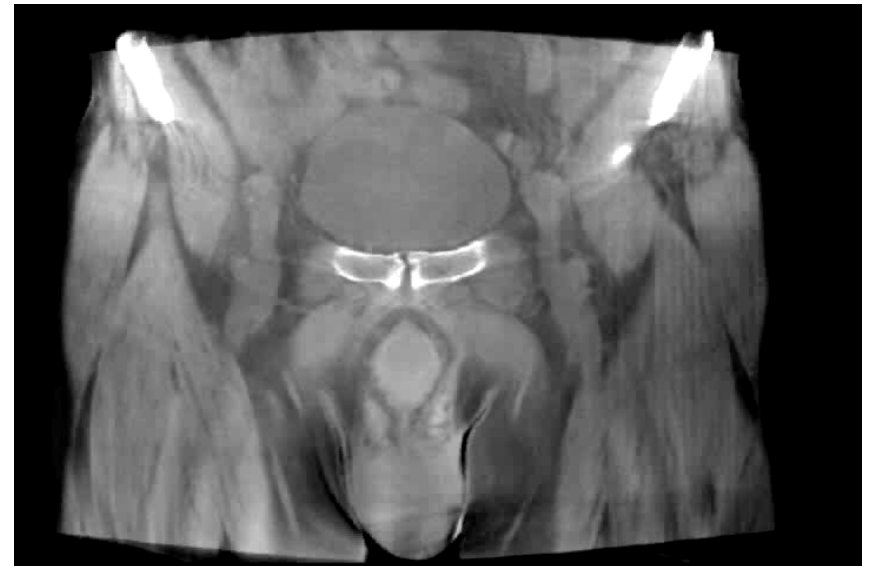
Prostate Cancer:
The Litmus Test

"The prostate cancer test will determine whether President Obama and Congress put together a bill that begins to fix the fundamental problem with our medical system: the combination of soaring costs and mediocre results. If they don't, the medical system will remain deeply troubled, no matter what other improvements they make."

At What Cost?

Average spending for two years of prostate cancer treatment, based on the initial strategy, for patients who have the disease diagnosed.

TREATMENT	AVERAGE COST
Watchful waiting Active plan to postpone intervention, usually with exams and testing.	$ 2,436
External beam radiation therapy Multiple doses of radiation over several weeks.	$12,224
Radical prostatectomy Complete surgical removal of prostate gland.	$22,921
Brachytherapy Implantation of radioactive seeds	$28,872
Intensity-modulation radiation therapy (I.M.R.T.) Advanced radiation beam therapy targeted at tumor.	$51,069

Sources: Alan Garber and Daniella J. Perlroth, Stanford; Dana P. Goldman, the RAND Corp.

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Tenets of CER for Radiation Oncology

- Prostate CA but one example of many utilizing high technology in Rad Onc

- Radiation Oncology ideal as model for EHR derived Comparative Effectiveness Research
  - Approx 70% or RO's use EHRs to support practices
  - EHRs in RO are largely standards-based
  - Two major RO EHR vendors

- Sustainable CER process depends on established data collection framework
  - As clinical discipline, RO is uniquely positioned to demonstrate proof of concept

- Rad Onc is relatively homogeneous microcosm of other specialties/domains

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Elekta's Radiation Oncology Data Alliance (RODA) Program

Overview and characteristics

- Pilot program, early stage of development
    - Began Oct 2008 as offshoot of more mature MO program
- Uses aggregate data collected in EHR in routine course of care
- Effort to demonstrate proof of concept for central RO data warehouse derived from live EHR systems
- Designed to readily scale
    - # data elements
    - # participants

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RODA Facility Goals

- Measure / improve data quality and quality of patient care

- Help ensure accurate and timely collection of patient data

- Develop and provide "best practice" standards for data collection

- Improve data capture by vis-à-vis "missing data" disclosure

- Increase/improve use of EMR by improving data capture

- Provide participant access to aggregate de-identified dataset

- Facilitate (clinical/administrative) research

- Help benchmark facilities against other de-identified facility aggregates

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RODA Global Goals

- Establish foundation for scalable (geographic, dataset, cross-vendor) RO registry program

- Establish model for whole-specialty "real-time" registry system

- Support academic data research programs

- Support clinical research for the benefit of RODA participants and the public (CER)

- Support USA-based quality (PQRI/CMS) and ASTRO practice-wide accreditation initiatives (PAAROT)

- Decrease global data collection expenses

RODA – A Novel Concept!
First discipline-wide EHR-derived central data registry ever

Disease-specific registry examples

- The National Familial Lung Cancer Registry, The Breast Cancer Family Registry, Breast and Colon Cancer Family Registries, USA and International Cancer Registry Programs

Treatment specific registry examples

- Open Heart Surgery Registry-NJ State Health Department, National Registry of CardioPulmonary Resuscitation (NRCPR), Anti-retroviral Pregnancy Registry

Specialty-wide, EHR-derived registry examples

- NONE?

RODA – A Novel Concept!
First discipline-wide EHR-derived central data registry ever

RO is well positioned for success

- <u>We're wired</u> - 70% of USA Rad Onc practices have dedicated Information Systems

- <u>We're data focused and driven</u> - Rad Onc's collect substantial clinical and technical data in routine course of care

- <u>We're standards-based</u> – Staging – UICC/AJCC; Image management - DICOM-RT

- <u>We're technology enlightened</u> – We understand the importance of data for advancement of clinical care and technological innovation

- <u>We're clinical</u> – We provide comprehensive clinical care from diagnosis to late follow-up

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RODA Architecture
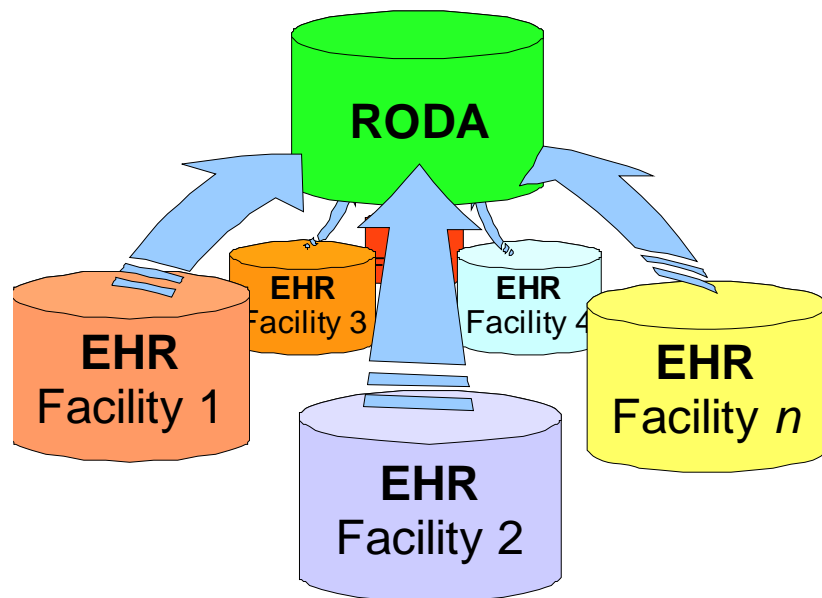
- Small program (dll) installed on local EHR PC

- MS Windows scheduled service runs monthly

- Data de-identified by dll locally prior to upload

- Uploaded via FTP/sFTP to server at Impac

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Collected Data Elements

- Pt. Demographics

- Pt. Diagnostics

- Lab data

- Tumor-specific information

- RT prescription and treatment information
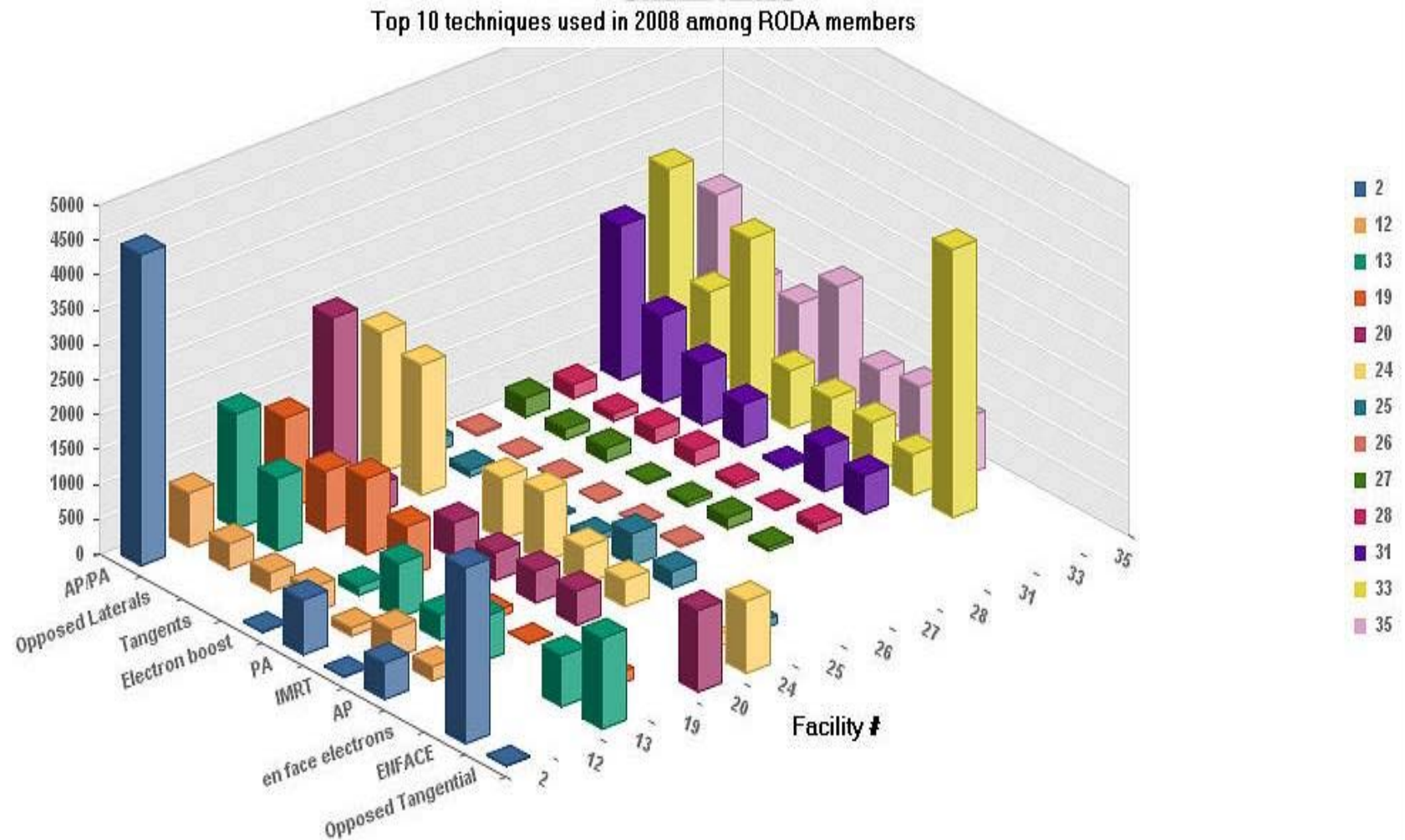
- Pt. Outcome/status

Dataset to scale with program

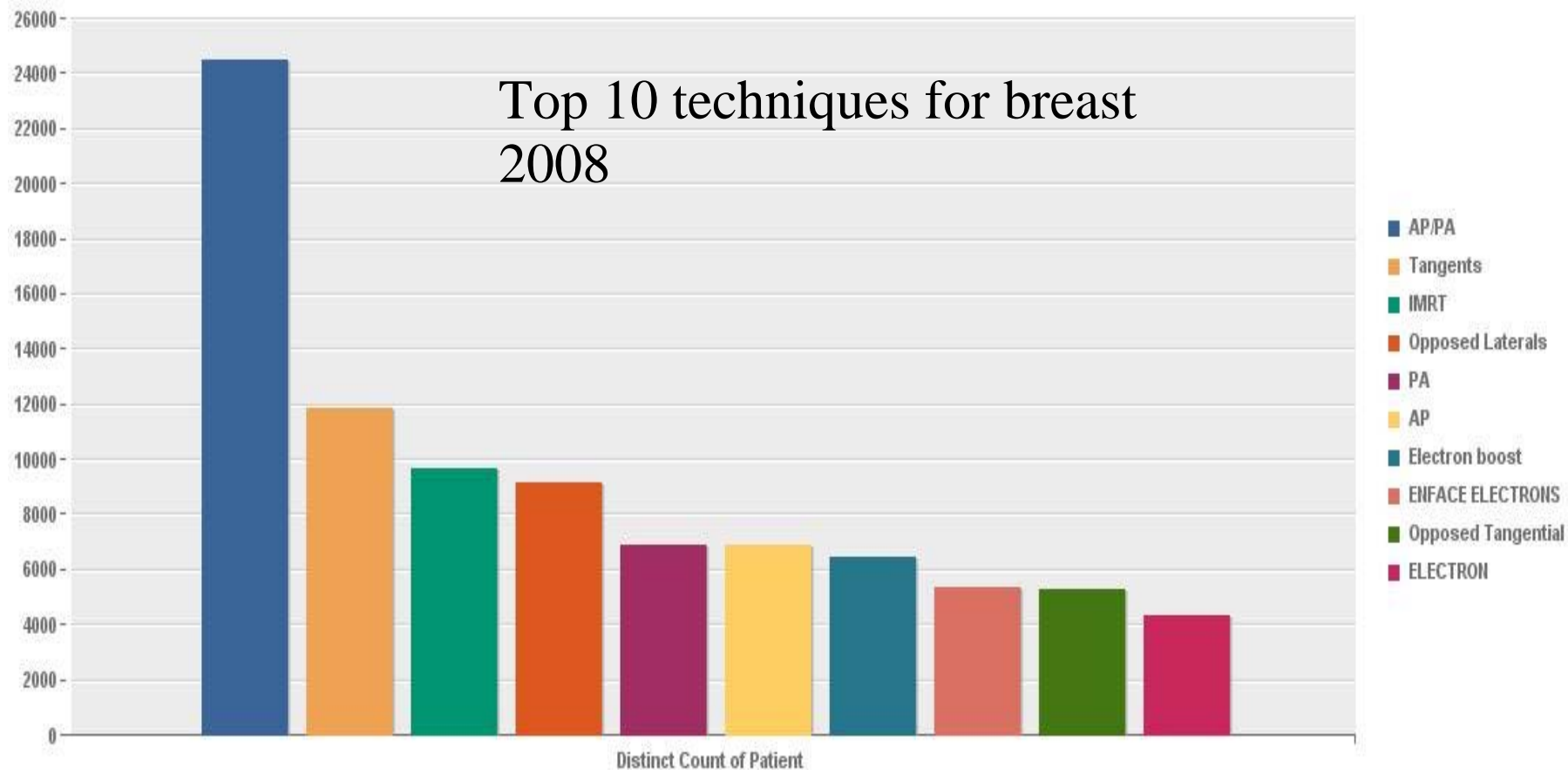| Medical and Radiation Oncology	Medical Oncology Only	Radiation Oncology Only
Patient Information • Patient sex • Patient race • Patient date of birth • Date of last contact • Vital status	**Chemo Course Information** • Start date of chemotherapy course • Drugs to be used in course • Patient status • Chemotherapy intent	**Radiation Course Information** • RT site (field) • Field definition • RT treatment intent • Start date • End date • Total dose • External beam • Fractionation scheme (pattern) • Fraction dose • Number of fractions • Energy (modality) • Dose action point • Dose rate • Dose spec • Technique • Region • Field size • Field depth • Angle • Care Plan name/ protocol ID

Tumor Information
• Date of diagnosis
• Tumor specifics
  • Site
  • Morphology
  • Grade
• Primary or recurrent site code
• Recurrence information
  • Type
  • Site
  • Date of recurrence
  • Stage group
	Drug Information
	• Drug code date administered
	• Route of administration
	• Number of drug administrations (days) in the cycle
	• Dosage given per administration (day)
	• Units for dosage
	• Calculated total dosage	

Lab Information • Date of lab test • Type of test • Results (value) • Units for results	**Cycle Information** • Start date of chemo cycle • Patient weight • Units for weight • Patient height • Units for height • BSA	

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Benchmarking Examples

Anatomical site and IMRT for 2008

Benchmarking Examples

Top 10 techniques used in 2008 among RODA members

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Benchmarking Examples

Top 10 techniques for breast
2008
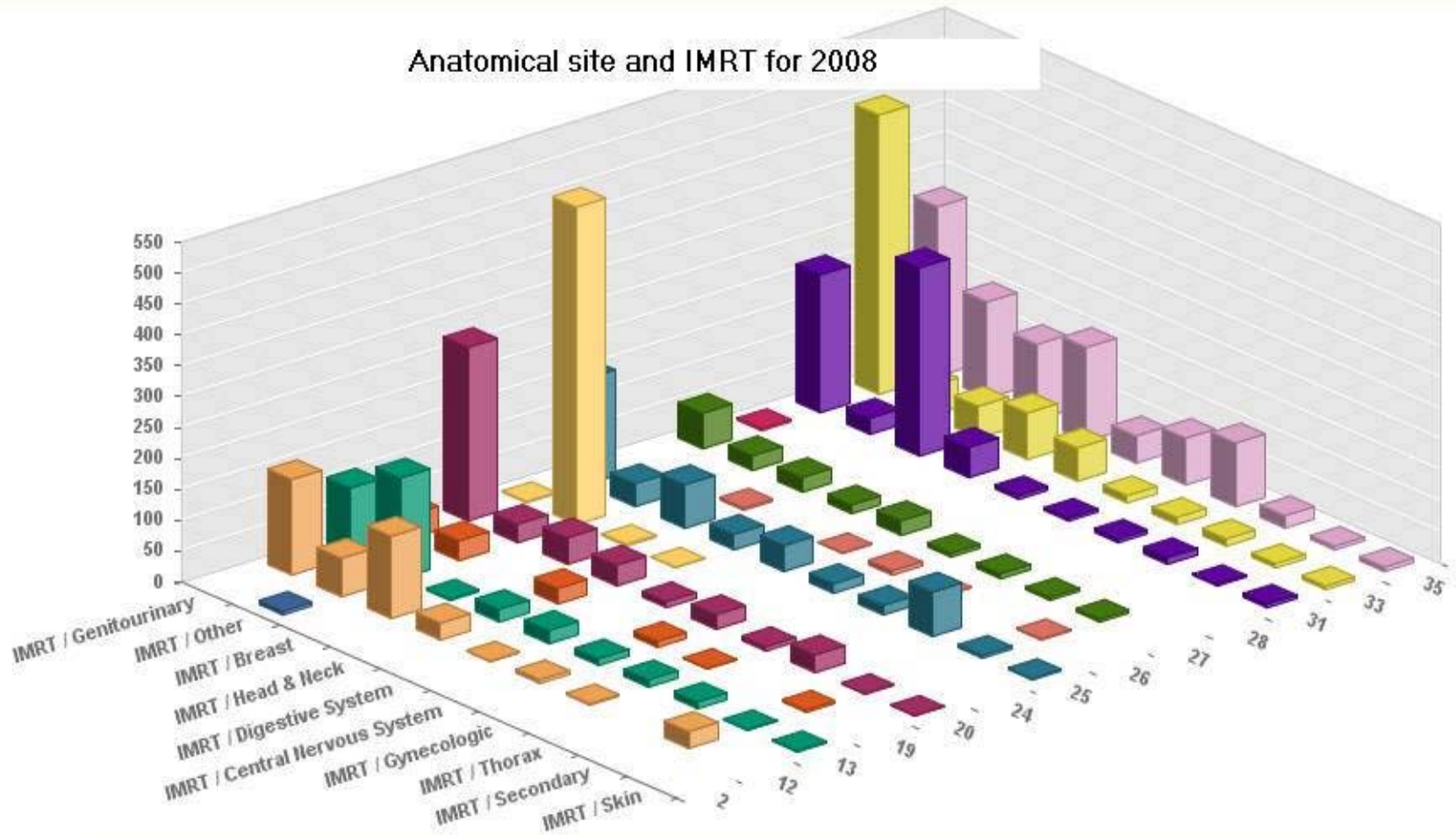
Data Quality: Data Completeness Form

RODA Program Status

- Current Participants
  - USA: 7 facilities
  - Approx 30 sites reviewing licenses in USA, Canada, New Zealand...

- Cooperation from other major oncology EHR vendors being sought
  - Plans for "neutral" data warehouse in development

ASTRO 2009 Abstract:

  - October 2008 – March 2009
  - 121,000 patient records, 108,000 patient treatments

Challenges

- Data quality
    - Date of Diagnosis: 29% complete
    - Overall Stage: 21% complete
    - Her2neu: 1%
    - Gleason Score: 10%

- So where are the data?
    - Incorrect field
    - Scanned reports (saved as images)
    - Dictations (free text)
    - Physician's head?

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Challenges

- ## Regulatory/Administrative
  - Fear or lack of understanding of HIPAA
  - IRB approval, legal agreements – time consuming

- ## Time to spend on data quality
  - Working with sites to enter the data correctly the first time
  - Few have time 'correct' missing/erroneous data

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In Summary

- Cancer as a Comparative Effectiveness Research Priority

- Radiation oncology is well poised for success

- Well poised, but still have problems getting quality data

- Elekta's RODA aims to help collect and improve data quality from the EHR thereby fostering CER

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QUESTIONS?

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