

# Subject-Related Site Metrics in Siebel CTMS



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October 2010



# Introduction

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- Extract Business Intelligence from CTMS on:
  - Program, Indication, Project
  - Country
  - **Site**
  - Investigator
  - CRA, CRO, Lab, IRB
- Operational (track progress)  
    AND Strategic (engage again?)



# Let's Concentrate on Sites

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- Enrollment
  - Milestone Tracking (FSI, LSI, LSO...)
- Queries
- Deviations
- Monitoring Performance



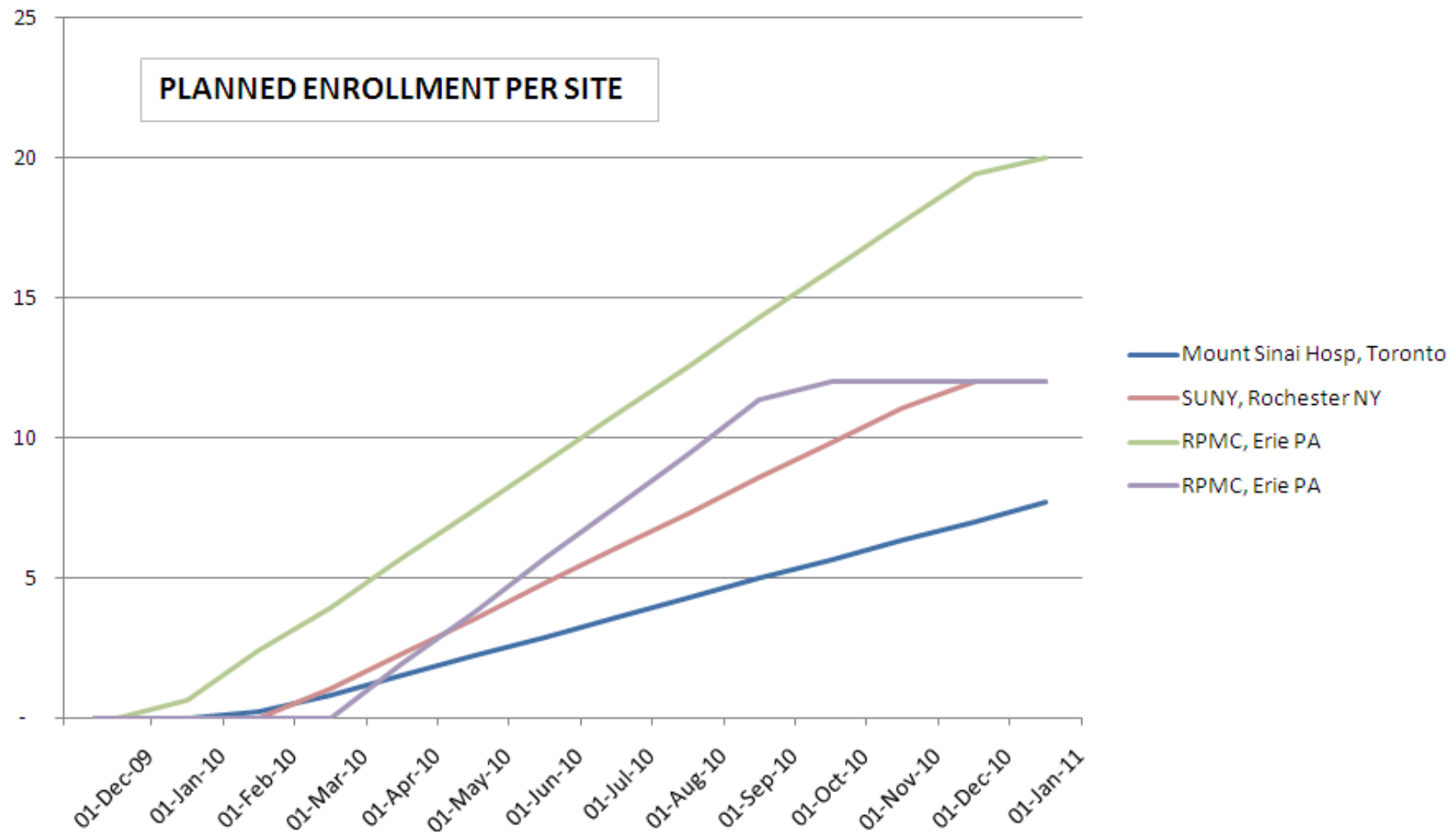
# Enrollment Modeling

- Given the number of expected subjects, and the FSI and LSI dates, we can evaluate the rate of enrollment

Site	Project	Planned	FSI Plan	FSI Actual	LSI Plan	LSI Actual	Date	Expected	Actual	Compliance	Status
Mount Sinai Hosp, Toronto ON	CBR-0098	12	12-Jan-10	23-Jan-10	12-Jul-11		11-Oct-10	6	6	100%	Green
Toronto General, Toronto ON	CBR-0098	8	09-Feb-10	05-Feb-10	13-Mar-12		11-Oct-10	3	2	67%	Red
McMaster Uni, Hamilton ON	CBR-0098	8	13-Feb-10	19-Feb-10	07-Nov-10		11-Oct-10	7	6	86%	Yellow
Seneca Regional, Buffalo NY	CBR-0098	16	09-Feb-10	09-Feb-10	19-May-11		11-Oct-10	8	8	100%	Green
Syracuse Uni, Syracuse NY	CBR-0098	12	04-Feb-10	04-Feb-10	25-Mar-11		11-Oct-10	7	7	100%	Green
Baycrest, Toronto ON	CBR-0098	12	15-Feb-10	18-Feb-10	04-Mar-12		11-Oct-10	4	5	125%	Green
Queens, Kingston ON	CBR-0098	4	10-Dec-09	19-Dec-09	14-Feb-10	07-Feb-10	11-Oct-10	4	4	100%	Green
SUNY, Rochester NY	CBR-0098	12	01-Feb-10	04-Feb-10	23-Nov-10		11-Oct-10	10	12	120%	Green
RPMC, Erie PA	CBR-0098	20	22-Dec-09	20-Dec-09	11-Dec-10		11-Oct-10	17	13	76%	Yellow
RPMC, Erie PA	CBN-1209	12	28-Feb-10	28-Feb-10	11-Sep-10	14-Sep-10	11-Oct-10	12	12	100%	Green
Mellon Uni, Pittsburgh PA	CBN-1209	16	14-Jan-10	15-Jan-10	28-Dec-10		11-Oct-10	12	11	92%	Yellow

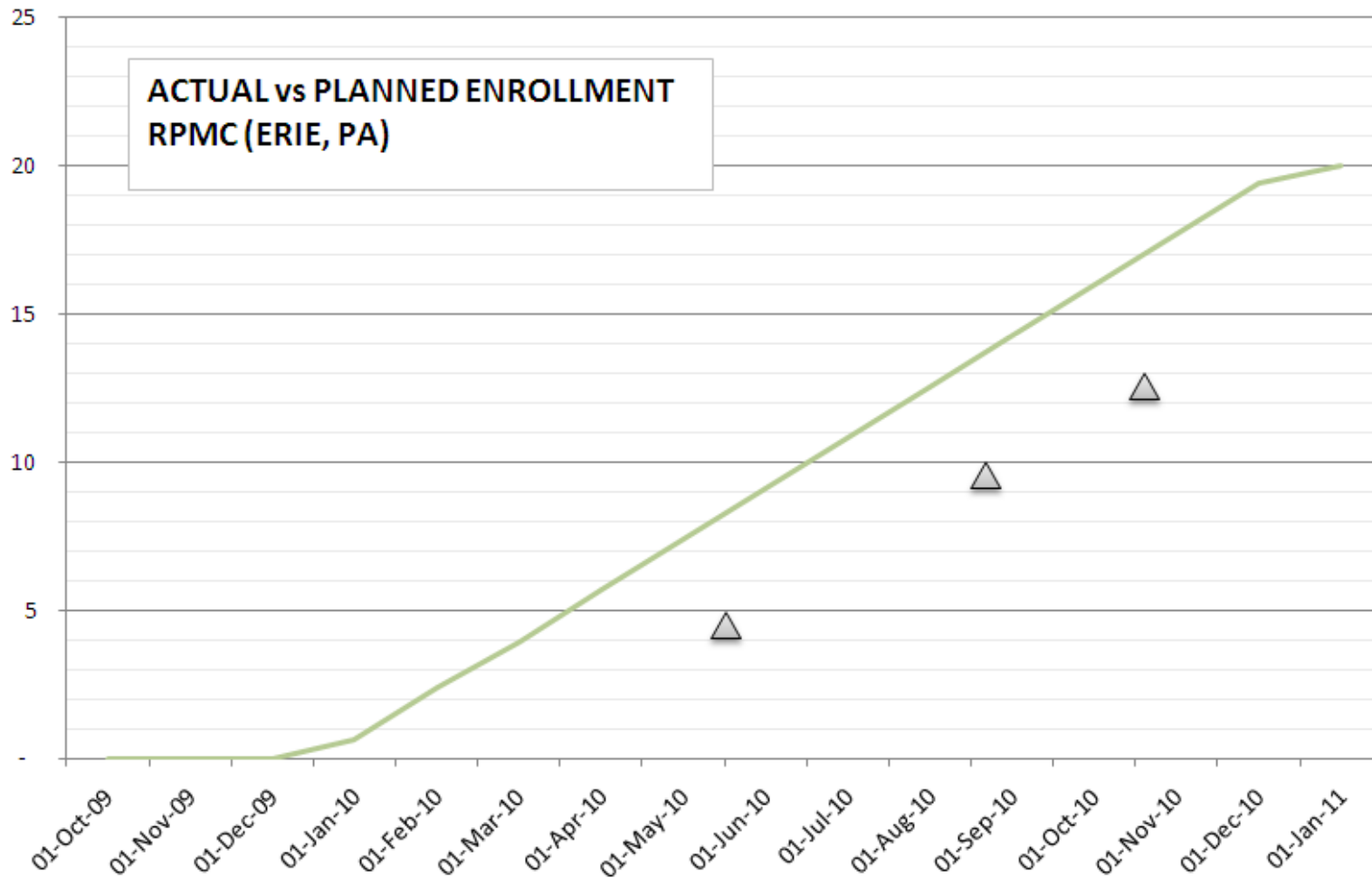


# Enrollment Modeling (cont.)





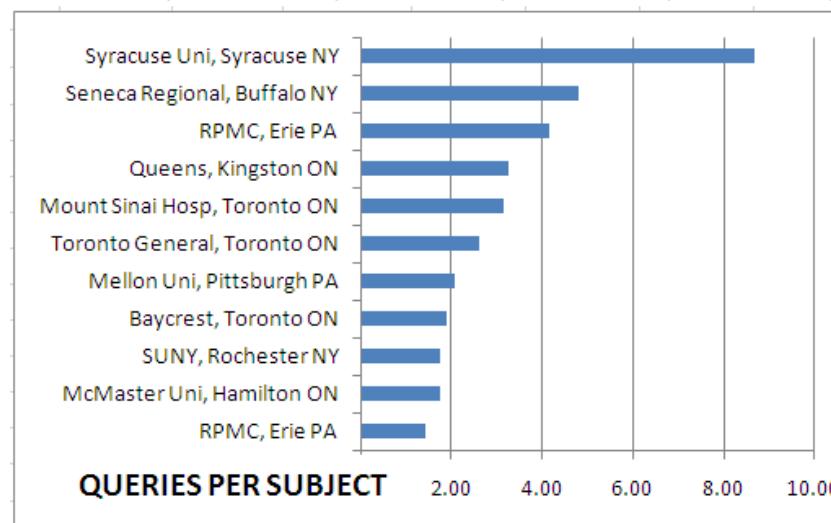
# Enrollment Modeling (cont.)





# Conduct Metrics: Queries

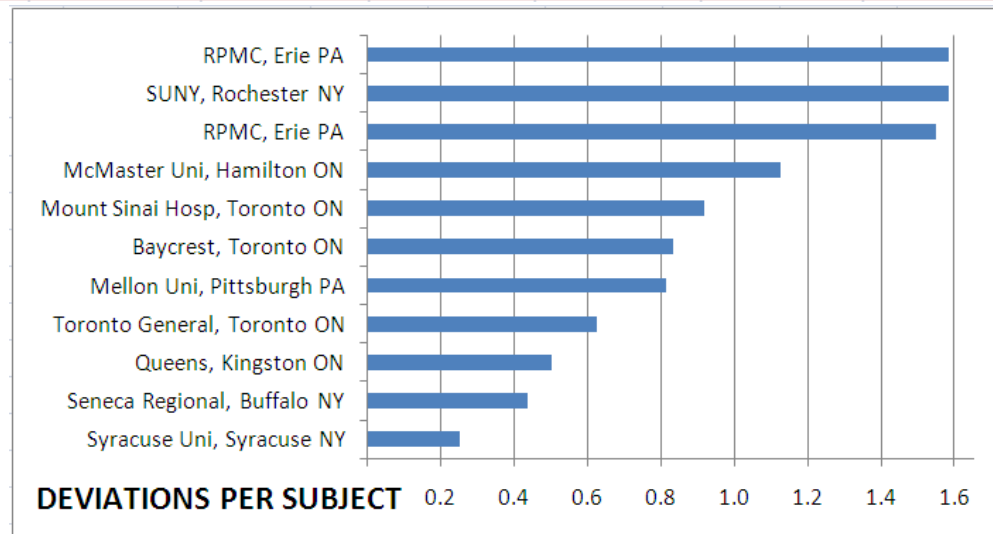
Site	Project	Subjects	Queries	Avg Time	Avg Rep	Max Rep	QPS
RPMC, Erie PA	CBR-0098	20	29	11.6	3.5	6	1.45
McMaster Uni, Hamilton ON	CBR-0098	8	14	7.2	2.6	6	1.75
SUNY, Rochester NY	CBR-0098	12	21	5.0	1.2	5	1.75
Baycrest, Toronto ON	CBR-0098	12	23	6.1	2.1	7	1.92
Mellon Uni, Pittsburgh PA	CBN-1209	16	33	13.9	2.2	5	2.06
Toronto General, Toronto ON	CBR-0098	8	21	7.6	1.5	5	2.63
Mount Sinai Hosp, Toronto ON	CBR-0098	12	38	4.1	1.8	5	3.17
Queens, Kingston ON	CBR-0098	4	13	3.8	1.7	3	3.25
RPMC, Erie PA	CBN-1209	12	50	8.9	3.0	8	4.17
Seneca Regional, Buffalo NY	CBR-0098	16	77	11.6	1.7	9	4.81
Syracuse Uni, Syracuse NY	CBR-0098	12	104	15.6	2.9	7	8.67





# Conduct Metrics: Deviations

Site	Project	Subjects	Deviations	Avg/Subj	Excl	GCP	Avg Impact	TTR
Syracuse Uni, Syracuse NY	CBR-0098	12	3	0.3	0	5	1.8	6
Seneca Regional, Buffalo NY	CBR-0098	16	7	0.4	1	2	1.5	12
Queens, Kingston ON	CBR-0098	4	2	0.5	0	0	2.0	14
Toronto General, Toronto ON	CBR-0098	8	5	0.6	0	1	2.7	11
Mellon Uni, Pittsburgh PA	CBN-1209	16	13	0.8	1	3	1.1	12
Baycrest, Toronto ON	CBR-0098	12	10	0.8	0	2	1.8	13
Mount Sinai Hosp, Toronto ON	CBR-0098	12	11	0.9	0	3	1.6	16
McMaster Uni, Hamilton ON	CBR-0098	8	9	1.1	0	0	1.8	9
RPMC, Erie PA	CBR-0098	20	31	1.6	2	1	2.0	9
SUNY, Rochester NY	CBR-0098	12	19	1.6	0	2	1.3	14
RPMC, Erie PA	CBN-1209	12	19	1.6	0	1	1.6	6







# Subject Visit Tracking

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- Expected schedule known per SVT
- Actual dates entered in CTMS
- Events to be modeled:
  - Compliance to dates
  - Compliance to treatment
  - Impact on site LSO



## **Conduct Metrics: CRF Collection**

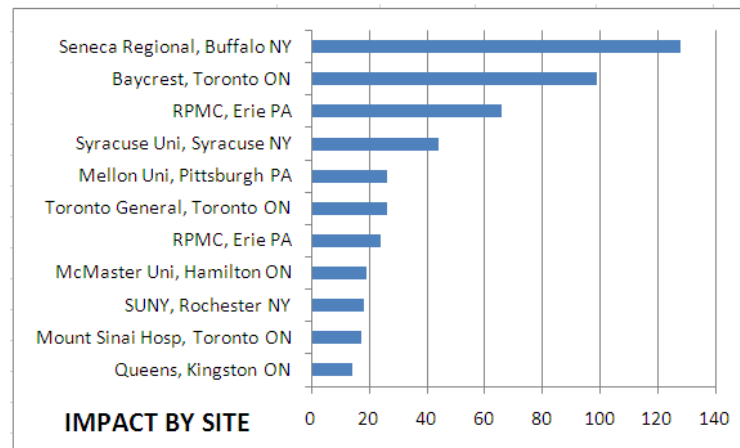
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- Difference between paper and EDC
- Penalties on missing pages
- Penalties on SDV issues
- Impact on interim analysis or database lock (cost model can incorporate time)



# CRF Collection Impact Metric

Site	Project	Subjects	LCVs	LCADs	LSO Plan	Impact
Syracuse Uni, Syracuse NY	CBR-0098	12	6	174	28-Oct-14	44
Seneca Regional, Buffalo NY	CBR-0098	8	4	132	28-Oct-15	128
Queens, Kingston ON	CBR-0098	8	2	48	07-Apr-14	14
Toronto General, Toronto ON	CBR-0098	16	11	188	16-May-14	26
Mellon Uni, Pittsburgh PA	CBN-1209	12	5	53	26-Sep-14	26
Baycrest, Toronto ON	CBR-0098	12	1	33	18-Nov-15	99
Mount Sinai Hosp, Toronto ON	CBR-0098	4	5	173	24-Jan-14	17
McMaster Uni, Hamilton ON	CBR-0098	12	11	201	03-Feb-14	19
RPMC, Erie PA	CBR-0098	20	14	255	07-Dec-14	66
SUNY, Rochester NY	CBR-0098	12	3	88	28-Apr-14	18
RPMC, Erie PA	CBN-1209	16	7	70	11-Aug-14	24





# Operational Implications

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- Score a site based on objective measures
- Site's capability card:
  - Cost
  - Equipment
  - Personnel qualifications
  - Operations performance
  - Invalidating factors



## Strategic Implications

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- Evaluate a site within a country
- Aggregate to regions or countries
- Map best locations per indication
  - “Site X is good for CNS indications and should be re-engaged, but for oncology it is dominated in all categories by site Y”
  - “Country A has a better combination of patient pools, site capabilities and costs than country B”