

# Controlling CRA Schedules and Anticipating Visit Load



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## Acknowledgments

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- Thanks to OHSUG for this opportunity to present for the CTMS focus group
- Thanks to the OHSUG Planning and Review Committee and Siebel Clinical CTMS Focus Group Chairs for their patience in receiving and reviewing this presentation



## The Context

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- Monitoring activities consume a significant part of the study budget
  - Drive to optimize
- Long-term and short-term planning of monitoring visits are separate activities:
  - Sponsor's view (monitoring plan – years)
  - CRA view (travel schedule – weeks)



## CTMS to the Rescue

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- Functions a CTMS can implement
  - Monitoring plan view
  - Resource Management view
  - CRA view (scheduling, pre-visit letter...)
  
- Communicate across functions for increased effectiveness

## **Scenarios (1)**

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- Only internal CRAs
- Internal CRAs vs contractors / CRO
  
- Assumptions implicit in model
  - Labor cost of each CRA type
  - Trustworthiness / FTE time supporting CRA

## **Scenarios (2)**

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- Degrees of freedom in scheduling visits
- Degrees of urgency in CRF collecting / SDV
  
- Implications
  - Quantifying cost of tardiness
  - Quantifying cost of missing data points



## Multi-Person Calendar (1)

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- Siebel's default Calendar can show one's own calendar or people reporting to me
  
- How about having a calendar showing several people at once?



## MPC (2): Required Data Entry

- Have CRA report on availability (by entering vacation time, training, other work)

Mon	Tue	Wed	Thu	Fri
<b>11</b> 0630 Travel 0900 Site 1003 TL-0984 1700 Travel	<b>12</b> 0700 Travel 0900 Site 1011 TL-0984	<b>13</b> 0900 Site 1011 TL-0984 1700 Travel	<b>14</b> 0800 Other Work	<b>15</b> 0800 Other Work
<b>18</b> 0700 Travel 1000 Site 257 TL-124 1500 Travel	<b>19</b> 0730 Training	<b>20</b> 0730 Training	<b>21</b> 0800 Bench Time	<b>22</b> 0700 Travel 1000 Site 1016 TL-0984 1700 Travel
<b>25</b> 0700 Travel 0900 Site 1014 TL-0984	<b>26</b> 0900 Site 1014 TL-0984 1700 Travel	<b>27</b> 0800 Vacation	<b>28</b> 0800 Vacation	<b>29</b> 0800 Vacation





# MPC (3): Multi-Person View

Week of May 11	
<b>11</b> ADR 0900 Site 1003 TL-0984 BN 0800 Site 4455 TL-124 RT Jury Duty	<b>Antonio D Ramirez</b> 0630 Travel 0900 Site 1003 TL-0984 1700 Travel
<b>12</b> ADR 0900 Site 1011 TL-0984 RT Jury Duty	
<b>13</b> ADR 0900 Site 1011 TL-0984 BN 0800 Site 4622 TL-124	



# MPC (4): Display

- Two main views:
  - CRA availability, incl. filter by site or by geography (e.g. FL, or FL+GA+AL)
  - CRA commitments: multi-CRA calendar

Project	Protocol Number	Site Number	Investigator Last	Investigator First	Site City	Site State	Country	Subjects Enrolled
>		X17-028	Tavernier	Bertrand			France	0
Test 1 delete		UB5ZK	Morse	Peter			USA	0
New Treatment Proj		0888	Gable	Clark			USA	0
Atomic Cafe		R4004	Selvaraj	Ahila			USA	10
Atomic Cafe		00563	Essig	Jason			USA	1



## Load Balancing (1)

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- “Assign CRAs to visits so that the amount of work is balanced across CRAs”
- Objective function: min Workload variance
- Constraints: Calendar entries
- Simplest solution: tally up all CRA loads, find max and min, and re-allocate visits
  - Each decision looks like “shift next monitoring visit to site 108 out of CRA2 and give to CRA5”



## Load Balancing (2)

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- “Assign work first to selected set of CRAs”
  - (Define cost function for each CRA)
- Objective function: min Cost
- Constraints: Calendar entries
- Simplest solution: Front-load best CRAs first
  - Each decision looks like “shift next visit to site X out of CRA26 and give to CRA1”



## Tools for Load Balancing

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- General Algorithm
  - Extract CRA reported time
  - Apply weights and estimate CRA loads
  - Balance according to pre-set criteria
- For more complex problems
  - Define objective and constraints
  - Export data to Optimization package
  - If needed, create a means to import back data to Siebel or to Analytics engine



## Annex: The Case for Rescheduling

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- Not enough subject visits available
  - Delay site visit
  - Telephone call instead of visit
- Multi-site trip feasibility
  - “Junkets” can be efficient
  - “The travelling CRA problem”



## Subject-Related Site Metrics in Siebel CTMS

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Thank You



Q/A



## Presenter Bio: Jason Essig

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Jason Essig is the Global Siebel Architecture & Technology Manager for DBMS Consulting.

Jason has over 12 years of Siebel design and configuration experience.

He has worked in the pharmaceutical industry for over six years, and has also worked on a variety of other applications such as Sales, Service, Call Center, and Marketing.

Jason's strengths include data integration, system architecture and design, database administration, and application development for UNIX and Windows platforms.





## Presenter Bio: Alex Platkin

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Alex Platkin is an Implementation Specialist with DBMS Consulting. Alex has sixteen years of industry experience working with several clinical data management systems, documentation management systems and the Siebel Clinical CTMS.

Alex's strengths include business analysis, system specification, and validation documentation.