EHR Usability Test Report of Radysans EHR version 3.0


Radysans EHR 3.0

Date of Usability Test: December 28, 2015
Date of Report: December 30, 2015
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Executive Summary

A usability test of Radysans EHR version 3.0 was conducted on December 28, 2015 in the offices of Radysans, Inc located at 1701 Center Street, Suite 200, Apex, NC by Radysans Usability research team. The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT).

During the usability test, 2 healthcare providers 6 other clinical and non-clinical users matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks.

This study collected performance data on 29 tasks typically conducted on an EHR:
- Electronic prescribing (314.b.3)
  1. Create prescriptions

- CPOE (314.a.1)
  2. Record Medication Order
  3. Change Medication Order
  4. Access Medication Order
  5. Record Laboratory Order
  6. Change Laboratory Order
  7. Access Laboratory Order
  8. Record Radiology Order
  9. Change Radiology Order
  10. Access Radiology Order

- Drug-drug, drug-allergy interactions checks (314.a.2)
  11. Create drug-drug and drug-allergy interventions prior to CPOE completion
  12. Adjustment of severity level of drug-drug interventions

- Medication list (314.a.6)
  13. Record Medication List
  14. Change Medication List
  15. Access Medication List
Medication allergy list (314.a.7)
16. Record Medication Allergy List
17. Change Medication Allergy List
18. Access Medication Allergy List

Clinical Decision Support (CDS) (314.a.8)
19. Problem List Interventions
20. Medication List Interventions
21. Medication Allergy List Interventions
22. Demographics Interventions
23. Lab Tests and Results Interventions
24. Vital Signs Interventions
25. Identify User Diagnostic and Therapeutic Reference Information
26. Configuration of CDS interventions by user

Clinical Information Reconciliation (314.b.4)
27. Reconcile patient’s active medication list with another source
28. Reconcile patient’s active problem list with another source
29. Reconcile patient’s active medication allergy list with another source

During the 90 minutes’ one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form. Participants were instructed that they could withdraw at any time. Participants had prior experience with some form of the EHR. The administrator introduced the test, and instructed participants to complete a series of tasks (given one at a time) using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task.

Participant screens and audio were recorded for subsequent analysis.

The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete each task (measured for successful task completion only)
- Participant’s verbalizations
• Participant’s satisfaction ratings of the system

We did not count errors. Instead, errors are reflected in task times and success rates. All participant data was de-identified—no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire and were compensated with $100 worth of gift voucher for their time.

Various recommended metrics, in accordance with examples set forth in the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

<table>
<thead>
<tr>
<th>Measure</th>
<th>N</th>
<th>Task Success (Binary)</th>
<th>Time on Task (Seconds)</th>
<th>Task Ratings (5=Easy)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create Prescriptions</td>
<td>1</td>
<td>87.50%</td>
<td>58</td>
<td>4.25</td>
</tr>
<tr>
<td>Record Medication Order</td>
<td>2</td>
<td>100.00%</td>
<td>55</td>
<td>4.5</td>
</tr>
<tr>
<td>Change Medication Order</td>
<td>3</td>
<td>100.00%</td>
<td>28</td>
<td>4.625</td>
</tr>
<tr>
<td>Access Medication Order</td>
<td>4</td>
<td>100.00%</td>
<td>18</td>
<td>4.625</td>
</tr>
<tr>
<td>Record Laboratory Order</td>
<td>5</td>
<td>100.00%</td>
<td>23</td>
<td>4.5</td>
</tr>
<tr>
<td>Change Laboratory Order</td>
<td>6</td>
<td>87.50%</td>
<td>13</td>
<td>3.875</td>
</tr>
<tr>
<td>Access Laboratory Order</td>
<td>7</td>
<td>100.00%</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Record Radiology Order</td>
<td>8</td>
<td>100.00%</td>
<td>18</td>
<td>4.75</td>
</tr>
<tr>
<td>Change Radiology Order</td>
<td>9</td>
<td>100.00%</td>
<td>15</td>
<td>4.75</td>
</tr>
<tr>
<td>Access Radiology Order</td>
<td>10</td>
<td>100.00%</td>
<td>12</td>
<td>5</td>
</tr>
<tr>
<td>Create drug-drug and drug-allergy interventions</td>
<td>11</td>
<td>87.50%</td>
<td>67</td>
<td>4.625</td>
</tr>
<tr>
<td>Adjustment of severity level of drug-drug interventions</td>
<td>12</td>
<td>75.00%</td>
<td>112</td>
<td>4.5</td>
</tr>
<tr>
<td>Task</td>
<td>Value</td>
<td>Percentage</td>
<td>Completion</td>
<td>Score</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-------</td>
<td>------------</td>
<td>------------</td>
<td>-------</td>
</tr>
<tr>
<td>Record Medication List</td>
<td>13</td>
<td>100.00%</td>
<td>35</td>
<td>4.75</td>
</tr>
<tr>
<td>Change Medication List</td>
<td>14</td>
<td>100.00%</td>
<td>30</td>
<td>4.625</td>
</tr>
<tr>
<td>Access Medication List</td>
<td>15</td>
<td>100.00%</td>
<td>21</td>
<td>4.75</td>
</tr>
<tr>
<td>Record Medication Allergy List</td>
<td>16</td>
<td>100.00%</td>
<td>56</td>
<td>4.375</td>
</tr>
<tr>
<td>Change Medication Allergy List</td>
<td>17</td>
<td>100.00%</td>
<td>43</td>
<td>4</td>
</tr>
<tr>
<td>Access Medication Allergy List</td>
<td>18</td>
<td>100.00%</td>
<td>10</td>
<td>4.75</td>
</tr>
<tr>
<td>Problem List Interventions</td>
<td>19</td>
<td>75.00%</td>
<td>210</td>
<td>4</td>
</tr>
<tr>
<td>Medication List Interventions</td>
<td>20</td>
<td>87.50%</td>
<td>118</td>
<td>3.875</td>
</tr>
<tr>
<td>Medication Allergy List Interventions</td>
<td>21</td>
<td>87.50%</td>
<td>80</td>
<td>4.25</td>
</tr>
<tr>
<td>Demographics Interventions</td>
<td>22</td>
<td>100.00%</td>
<td>30</td>
<td>4.5</td>
</tr>
<tr>
<td>Lab Tests and Results Interventions</td>
<td>23</td>
<td>75.00%</td>
<td>28</td>
<td>4.5</td>
</tr>
<tr>
<td>Vital Signs Interventions</td>
<td>24</td>
<td>100.00%</td>
<td>26</td>
<td>5</td>
</tr>
<tr>
<td>Identify User Diagnostic and Therapeutic Reference Information</td>
<td>25</td>
<td>75.00%</td>
<td>48</td>
<td>4.375</td>
</tr>
<tr>
<td>Configuration of CDS interventions by user</td>
<td>26</td>
<td>100.00%</td>
<td>96</td>
<td>4.5</td>
</tr>
<tr>
<td>Reconcile patient’s active medication list with another source</td>
<td>27</td>
<td>87.50%</td>
<td>120</td>
<td>4.25</td>
</tr>
<tr>
<td>Reconcile patient’s active Problem list with another source</td>
<td>28</td>
<td>87.50%</td>
<td>56</td>
<td>4.375</td>
</tr>
<tr>
<td>Reconcile patient’s active medication allergy list with another source</td>
<td>29</td>
<td>100.00%</td>
<td>26</td>
<td>4.5</td>
</tr>
</tbody>
</table>
The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be: 93.50

Performance data and qualitative observations indicate the following key points:

- Major findings
  - Overall response from the users was very positive and they found the system to be very easy to use.

- Areas for improvement
  - Consistency of labelling and the placement of buttons will reduce the overall time and improve the efficiency.
  - Since there were many ways of accessing a particular task, users are not always selecting or aware of the optimal navigation for their workflow. Need to address this in Training and Implementation process.

**Introduction**

The EHRUT tested for this study was a pre-release instance of Radysans EHR Version 3.0, an EHR and clinical cycle management solution designed to help deliver increased revenue, decreased cost, and increased clinical control to healthcare providers in ambulatory setting. The EHRUT consists of the complete EHR system and the usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test the usability of the current user interface, and to provide evidence of usability in the EHR Under Test (EHRUT). To this end, measures of effectiveness, efficiency, and user satisfaction, such as success rate, time on task, and perceived task difficulty, were captured during the usability testing.

**Method**

**Participants**

A total of 8 participants, 2 healthcare providers 6 other clinical and non-clinical users, were tested on the EHRUT. Participants were recruited by the Usability research team and were compensated for their time with gift vouchers. Participants had no direct connection to the development of Radysans EHR. Participants were not from the vendor organization. All are familiar with EHR and work in ambulatory settings, either full time or part time.
Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment criteria. The following is a table of participants by characteristics, including demographics, professional experience, and experience with the EHRUT. Participant names were replaced with Participant IDs so that an individual’s data cannot be tied back to individual identities.

<table>
<thead>
<tr>
<th>Part. ID#</th>
<th>Gender</th>
<th>Age Range (years)</th>
<th>Occupation</th>
<th>Professional Experience (years)</th>
<th>Product Experience</th>
<th>Assistive Technology Needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Female</td>
<td>46-55</td>
<td>MD</td>
<td>20</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>2</td>
<td>Male</td>
<td>46-55</td>
<td>MD</td>
<td>24</td>
<td>6 months</td>
<td>None</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>36-45</td>
<td>Nurse/Clinical</td>
<td>16</td>
<td>1 – 2 yrs</td>
<td>None</td>
</tr>
<tr>
<td>4</td>
<td>Female</td>
<td>26-35</td>
<td>Non-Clinical</td>
<td>8</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>5</td>
<td>Male</td>
<td>56-65</td>
<td>Nurse/Clinical</td>
<td>33</td>
<td>12 months</td>
<td>None</td>
</tr>
<tr>
<td>6</td>
<td>Female</td>
<td>26-35</td>
<td>Nurse/Clinical</td>
<td>12</td>
<td>3 months</td>
<td>None</td>
</tr>
<tr>
<td>7</td>
<td>Female</td>
<td>36-45</td>
<td>Nurse/Clinical</td>
<td>10</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>8</td>
<td>Female</td>
<td>36-45</td>
<td>Non-Clinical</td>
<td>3</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Eight participants were recruited, and all participated in the usability test.

Participants were scheduled for 45-minute sessions, with 15 minutes between sessions for debrief by the moderator and data loggers, and to reset systems to proper test conditions.

**Study Design**

Overall, the objective of this test was to uncover areas where the application performed well—that is, effectively, efficiently, and with satisfaction—and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs, using the same tasks, the same data, the same types of participants, the same testing conditions, the same level of training and product customization/configuration, and the same style of test administration.

During the usability test, participants interacted with the EHRUT. Each participant was provided with the same instructions. The system was evaluated for effectiveness, efficiency, and satisfaction as defined by measures collected and analyzed for each participant:
• Number of tasks successfully completed within the allotted time without assistance
• Time to complete each task
• Participant’s comments
• Participant’s satisfaction ratings of the system

Tasks
A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR.
• Use electronic medical records system to order medications (314.b.3, and 314.a.1)
• Use electronic medical records system to configure/use Drug-Drug, Drug-Allergy interactions checks (314.a.2)
• Use electronic medical records system to enter patient medications (314.a.6)
• Use electronic medical records system to enter patient allergy items (314.a.7)
• Use electronic medical records system to order laboratory studies (314.a.1)
• Use electronic medical records system to order radiology studies (314.a.1)
• Use electronic medical records system to configure and use CDS (314.a.8)
• Use electronic medical records system to reconcile incoming patient information (314.b.4)

The tests the participants performed were given in accordance with the risk associated with user errors. Medication CPOE ordering was the highest on the list of items to evaluate, per the risk involved with incorrectly prescribing. Not having the methods to prescribe readily accessible could deter users from using the software, or could potentially incorrectly prescribe a medicine, slowing down the care they provide, or potentially endangering a patient. Following CPOE ordering, was the Medications list, and Allergy list items. We concluded these two tests were more critical than lab ordering, or radiology ordering, per incorrect data could lead to potentially incorrectly prescribing medicines, which could be fatal.

Procedures
The session started with the moderator verifying the participant’s identity, reviewing instructions regarding testing, and conducting a 20-minute walkthrough of the system. This walkthrough is not representative of the training available to new users of the system. Each participant reviewed and signed an informed consent and release form. Participants were then
assigned a participant ID. To ensure that the test ran smoothly, two staff members participated in this test, the usability administrator and the data logger. The usability testing staff conducting the test were experienced usability practitioners with a combined 15 years of experience practicing medicine. The administrator moderated the session including administering instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. A second person served as the data logger and took notes on task success, number and type of errors, and comments.

Participants were instructed to perform the tasks:

- As quickly as possible while completing tasks accurately
- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think-aloud technique.

For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task. Following the session, the administrator gave the participant the post-test questionnaire, and thanked each individual for their participation. Participants’ demographic information, task success rate, time on task, errors, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

**Test Location**

The test facilities included a quiet testing room with a table, computer for the participant, and computer for the administrator. Only the participant and administrator were in the test room.

To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

**Test Environment**

The EHRUT would typically be used in healthcare office/facility. Testing was conducted at Radysans offices. All participants were given a PC running windows and they have used mouse and keyboard when interacting with EHRUT. The EHRUT used the standard resolution and color settings of the moderators’ laptops – typically around 1280 x 1024. The application is a Web application. The application itself was accessed through a current version of the internet explorer, using a test instance over a secure internet connection. Before testing began, moderators logged into a test tablespace,
which contained fabricated data in a minimally configured, fictional practice. Participants did not change any default display settings.

**Test Forms and Tools**

During the usability test, various documents and instruments were used, including:

1. Informed Consent form, in a survey
2. Pre-test demographic survey
3. Moderator’s guide
4. Acknowledgement Form
5. System Usability Scale questionnaire

The moderator’s guide was devised so the moderator could note participant behavior, testing issues, and other observations.

The participant’s interaction with the EHRUT was captured and recorded digitally with Recorder running on the test machine. Verbal comments were recorded with a microphone.

**Participant Instructions**

The orientation to the study informed participants that testing goal was to measure the usability of Radysans EHR for specific tasks, that measurements such as time on task would be taken, that the data would be used in aggregate form only, and that their data would not be associated with their names. Participants were reminded that their participation was voluntary and that they could withdraw at any time. The administrator stressed that, so that the data could be aggregated in a meaningful way, participants would be working with a minimally configured practice, and participants were asked to complete the tasks exactly as presented to them. The orientation also let participants know the sessions would be recorded, with their permission, and that recordings would be used only to capture the data, would not be associated with their names, and would not be viewed by those not involved with this study.

The moderator read the following instructions:

> Thank you for participating in this study. Your input is very important to us. Today, we are measuring the usability of some specific tasks in Radysans EHR. We are having multiple people complete identical tasks, to get average task times and other measurements, so we don’t want you to think aloud in this study. Keep in mind that we are not evaluating your performance, but the usability of the Radysans EHR product.
I’ll give you instructions regarding the tasks, and I’ll ask you to complete tasks we have prepared. Once you have completed all of the tasks, I’ll ask for your feedback. The session should last no more than 60 minutes. You can take a break if you need one, and you can end the session at any time.

Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it, so please be honest with your opinions. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time. Should you feel it necessary you are able to withdraw at any time during the testing.

At this point training was presented, participants were shown Radysans EHR and as their first task, were given 10 minutes to explore the system and make comments. Once this task was complete, the administrator gave the following instructions:

For each task, I will read the description to you and say “Start.” At that point, please perform the task and say “Done” once you believe you have successfully completed the task. I would like to request that you not talk aloud while you are doing the tasks. I will ask your impressions about the task once you are done. Participants were then given 29 tasks to complete.

Usability Metrics

According to the NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency, and user satisfaction were captured during the usability testing.

The goals of the test were to assess:

1. Effectiveness of Radysans EHR by measuring participant success rates
2. Efficiency of Radysans EHR by measuring the average task time.
3. Satisfaction with Radysans EHR by measuring ease of use ratings for each task and the System Usability Scale at the end of the study.

Data Scoring

The following table details how tasks were scored, errors evaluated, and the time data analyzed.
<table>
<thead>
<tr>
<th>Measures</th>
<th>Rationale and Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness:</td>
<td>A task was counted as a success if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of participants who attempted that task. The results are provided as a percentage. The margin of error for tasks success was calculated using a 95% confidence level. Task times for successes were included in analysis. No optimal task times were benchmarked for the study.</td>
</tr>
<tr>
<td>Task Success</td>
<td></td>
</tr>
<tr>
<td>Effectiveness:</td>
<td>If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as a failure. Task times for failures were excluded from task time aggregation.</td>
</tr>
<tr>
<td>Task Failures</td>
<td></td>
</tr>
<tr>
<td>Efficiency:</td>
<td>Each task was timed from when the participant was instructed to “Start” until the participant completed the task. Only task times for tasks that were successfully completed were included in the task time analysis. Average time per task was calculated for each task. The margin of error for task times was calculated using a 95% confidence level.</td>
</tr>
<tr>
<td>Task Time</td>
<td></td>
</tr>
<tr>
<td>Satisfaction:</td>
<td>Participant’s subjective impression of the ease of use of the application was measured by administering both a simple post-task question and a post-session questionnaire. After each task, the participant was asked to rate, “Overall, this task was:” on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. Margin of error was calculated with a 95% confidence level.</td>
</tr>
<tr>
<td>Task Rating</td>
<td></td>
</tr>
</tbody>
</table>

**Results**

**Data Analysis and Reporting**

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Task data for individual participants was excluded from the analysis if the participant did not or could not follow the instructions for the task.

The usability testing results for the EHRUT are detailed below. The results should be seen in light of the objectives and goals outlined in the Study Design section.
The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be 93.50

**Discussion of the Findings**

These following sections describe the findings from the study.

**Effectiveness**

Based on the success data, participants effectively completed most tasks relatively successfully. The success rate for majority of the tasks was above 90%; Noting that users first-time use with this version of the product and limited training on the system, the software did very well and finding from the study are very informative.

**Efficiency**

Based on the observations of the task times, participants were able to complete tasks somewhat efficiently. Task times reflect first use. We expect task times to improve as users learn the system.

**Satisfaction**

Based on the task ratings, participants subjectively rated the EHRUT relatively easy to use. Average task ease-of-use ratings for all tasks were above 4.5 on a scale of 5.

Radysans, Inc is satisfied with overall results and feedback received from this study. It attested that the EHRUT is easy to use and also revealed some areas for further improvement.

**Major Findings**

Very positive feedback and high ease of use ratings. For first-time users with little training, the system fared fairly well on most tasks. Task times for successful participants were reasonable for first-time use; additional testing is needed for task efficiency for experienced users.

**Areas for Improvement**

Consistency of labelling and the placement of buttons will reduce the overall time and improve the efficiency.
Since there were many ways of accessing a particular task, users are not always selecting or aware of the optimal navigation for their work flow. Need to address this in Training and Implementation process.

While this study did not enumerate errors, task failure could have been avoided with better error prevention with a meaningful message in the system.
ATTN: Drummond Group, LLC
13359 North Hwy. 183
Suite B 406-238
Austin, TX 78750

January 18, 2016

Reg: Quality Management System [170.314.g.4]

We, Radysans Inc, utilize a home grown Quality Management System (QMS) that is modeled after best known practices within the software development industry. We used proven approaches and process frameworks, such as the agile development and Capability Maturity Model Integration (CMMI) and designed our QMS system specific to healthcare industry based on our experience. We use it in development, testing, implementation, and maintenance for all modules in Radysans EHR. This applies to all of the criteria/modules for which Radysans is applying for 2014 ONC certification.

Sincerely,

Mohan Dommaraju
Vice President
Mohan Dommaraju  
Vice President  
Radysans, Inc  

December 16, 2015  

Dear Gary Isaac,  

[Include the following information based on the EHR System under Test’s functionality]  

1. Are default settings for audit log and audit log status record are enabled by default?  
   Yes. The audit log is enabled by the application by default and users will not have the  
   option/settings to turn it off.  
   [IN170.314(d)(2)-1.01-1.02]  

2. Is encryption of electronic health information on end-user devices is enabled by default?  
   No. The EHR doesn’t store data in end-user devices because the EHR is pure web based  
   application and we prevent all caching of data from the browser.  
   [IN170.314(d)(2)-1.03/DTR 170.314.d.7-4]  

3. Does the EHR SUT allow a user to disable the following?  
   - audit log  
   - audit log status  
   - encryption status  
   [IN170.314(d)(2)-2.02 / IN170.314(d)(2)-2.09]  
   No.  

4. Does the EHR SUT permit any users to delete electronic health information?  
   [IN170.314(d)(2)-3.04]  
   No. only inactivation is possible.  

5. Describe how the audit logs are protected from being changed, overwritten or deleted  
   by the EHR technology.  
   [IN170.314(d)(2)-4.01]  
   Each audit log [insert, update, inactive, active] record is written through a stored  
   procedure in the database which is physically not accessible for any user. Hence no  
   record can be deleted, changed, or overwritten intentionally or accidentally.
6. Describe how the EHR is capable of detecting whether the audit logs have been altered. [IN170.314(d)(2)-5.01]

The audit logs are inside a separate table not accessible by the users and is out of bounds for the company staff also. The server is hosted in well protected anti-hackable environment.

Sincerely,

Mohan Dommaraju