



**Integrating  
Treatment Protocol  
Monitoring System  
with Real-Time  
Statistics: A  
Research Oriented  
In-House developed  
Solution.**

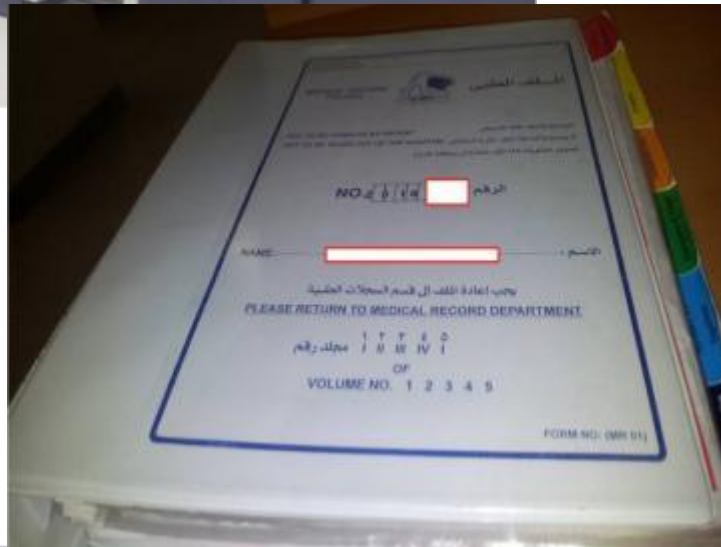
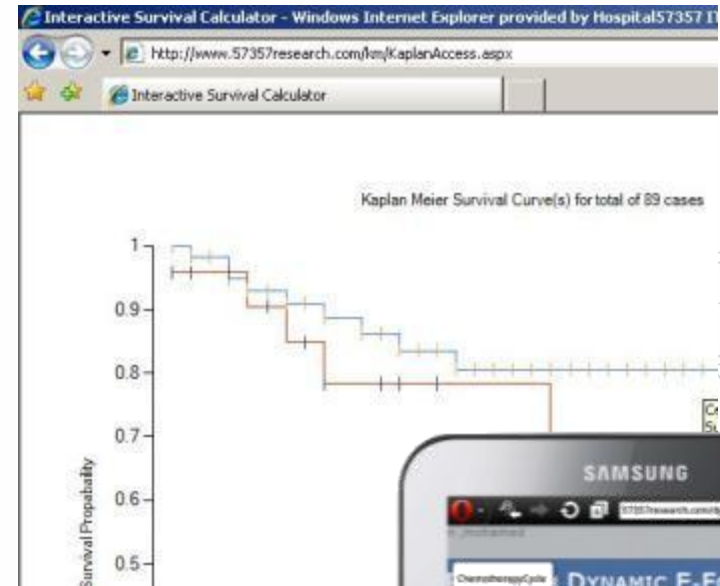




# In Three Years

From

To



2011

2008



# The Story of Transition

## Clinical

- **2007-2009**
  - Paper based patient charts.
- **2009**
  - Implementation of Cerner Millennium Electronic medical Record.

## Research

- **2007-2008**
  - Excel
- **2008-2009**
  - Access databases (local)
  - Databases shared over network.
- **2009**
  - In-House development of Web-based application for electronic data capture.
- **2010**
  - Development of Web-based plug-in for mobile / handheld devices and real-time analysis.
- **2012**
  - Joining RedCap open source Consortium



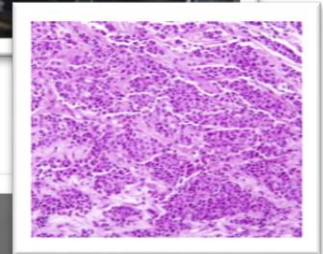
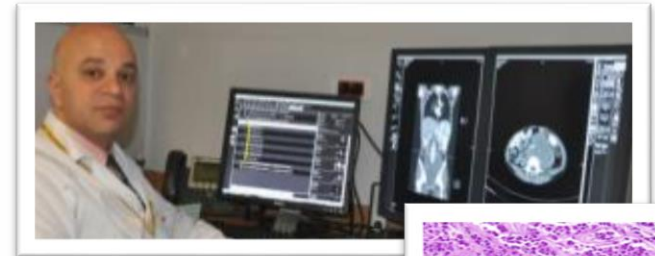
□ At Children's Cancer Hospital Egypt (CCHE) 57357, each individual pediatric malignancy is managed through a Disease Strategy Team.



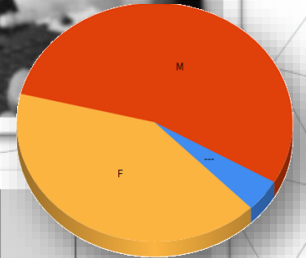


- The complexity of care and the inter-dependence of different disciplines required an implementation of a Hospital Information System that served only the clinical needs.

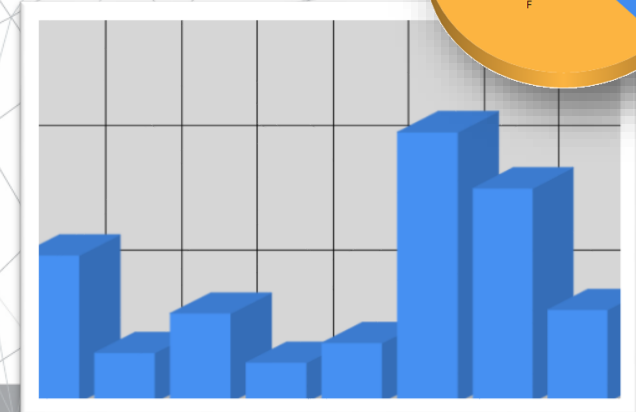
- Hospital Electronic Medical Record System



- Monitoring of treatment protocols as well as real-time follow-up were necessary to fulfill research needs and longitudinal outcome assessment.



- Research Information System (Our discussion today)





# Action

- We started to develop our own system for covering above mentioned issues





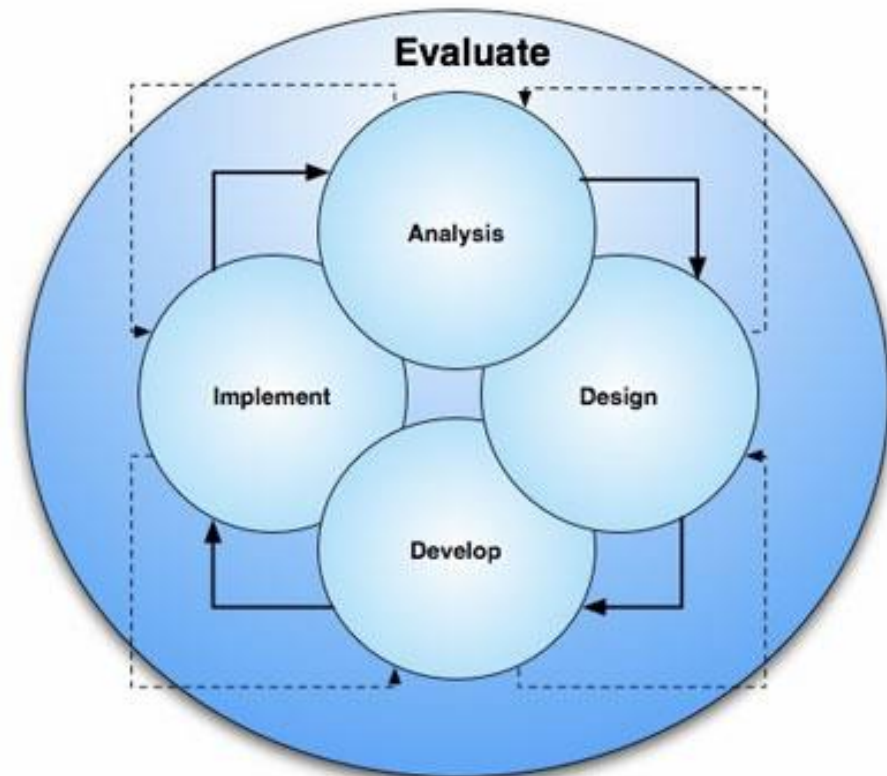
# System Objectives

- Ensuring that patients are accurately receiving their assigned protocol-based treatment.
- Monitoring and reducing protocol violations.
- Real-time data validation and statistical analysis.



# Methodology

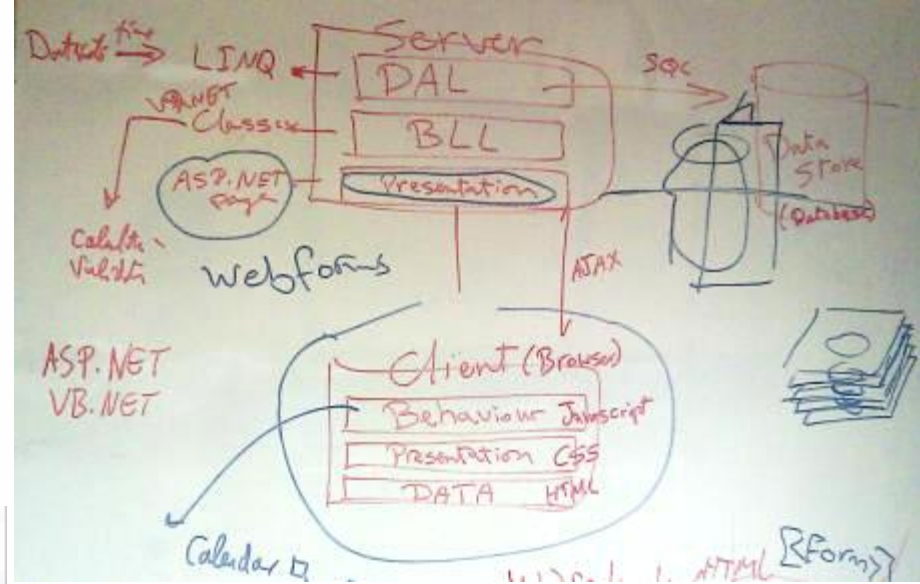
- ❑ Our team started with Brain Tumor Database as a Pilot Project, followed by the rest of pediatric malignancies.
- ❑ Followed structured methodology in Analysis, Design, Development, Implementation and Evaluation.
- ❑ We Took into consideration the HIPAA recommendations and the FDA - Code of Federal Regulations' requirements.



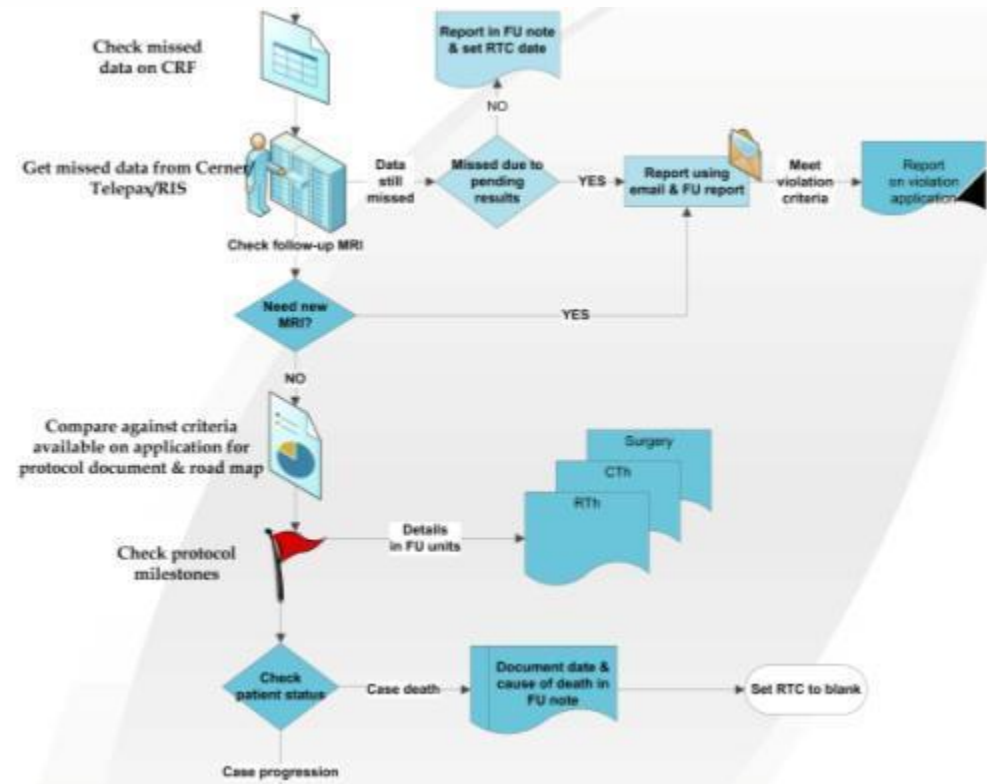
*\*HIPAA: Health Insurance Portability and Accountability Act*



# Analysis



- Define Scope, Analyze user needs and create a detailed Functional Requirements Document.





# Our system requirements

## Analysis phase

### I. Treatment Related Requirements

### II. Research Related Requirements





# Treatment Related Requirements

- Standard treatment Roadmaps needed to be monitored at pre-defined protocol milestones in order to minimize protocol deviations and violations.
- The Healthcare team needed a Central Protocol and Roadmap repository to avoid the use of outdated versions.

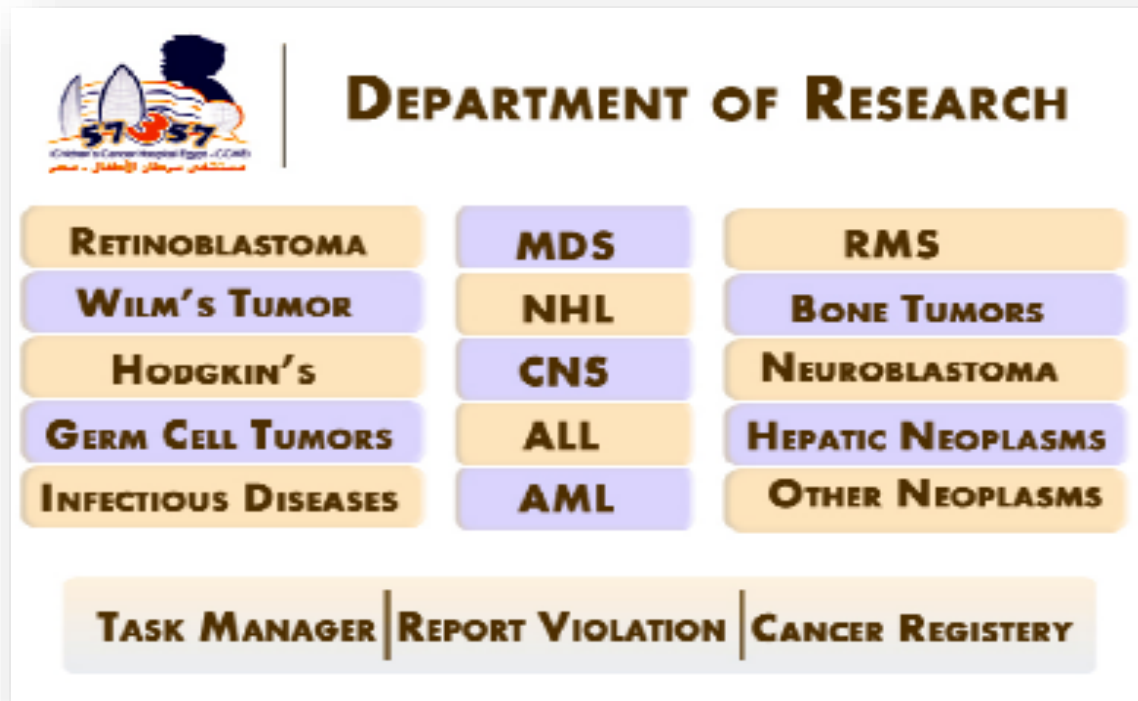


# Research Related Requirements

- **Semantic/structured:** The Hospital's EMR provided built-in templates for Clinical Documents that served clinical but not research needs, especially in case of unstructured free text entries. (e.g. Pathology Reports)
- **Scheduling/Milestones:** The EMR was not designed to capture data at specific treatment milestones. Data retrieval was not feasible in the format needed for outcome analysis.



Managing research data while keeping a simple, user friendly interface was a challenge and a motive to develop the monitoring solution.





# Design

- Transform detailed Requirements into complete detailed System Design Document.

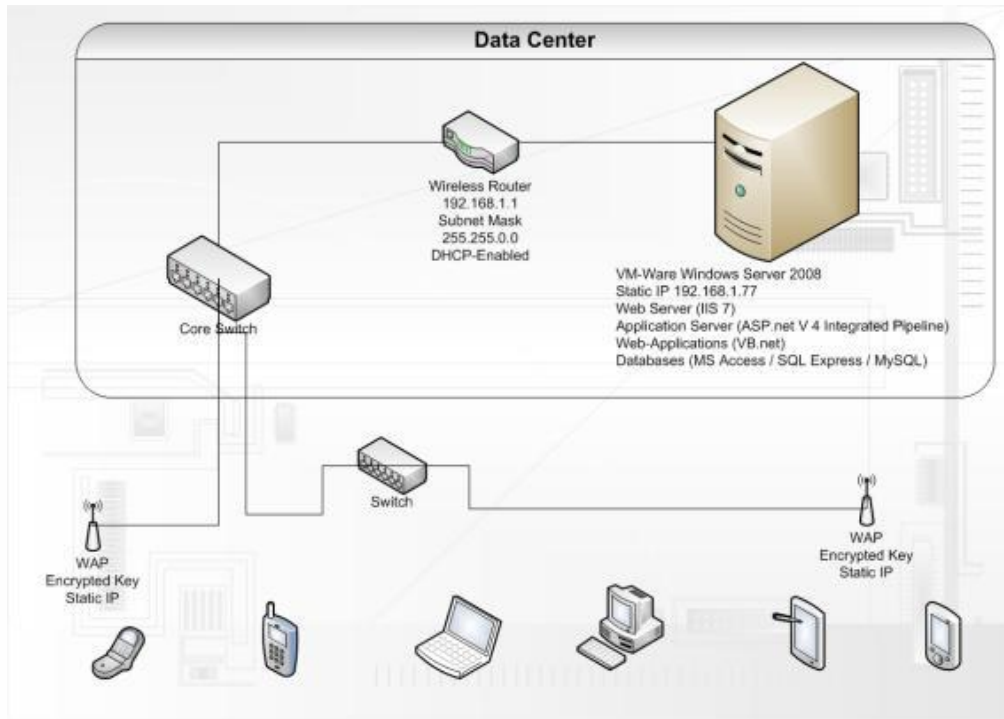


Table: Attachments

MainCRSAttachments



Attributes: Enforced, Cascade Updates, Cascade Deletes  
RelationshipType: One-To-Many

site/MainCRS



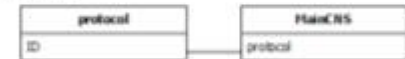
Attributes: Not Enforced  
RelationshipType: One-To-Many

pathology/MainCRS



Attributes: Not Enforced  
RelationshipType: One-To-Many

protocol/MainCRS



Attributes: Not Enforced  
RelationshipType: One-To-Many



# Development

- HIPAA\* compliant, Secured and Role Based Application.
- The solution allowed accessibility to researchers' friendly views of patients' data.
- Being developed "In-House", the system was cost effective and tailored to CCHE's needs.

*\*HIPAA: Health Insurance Portability and Accountability Act*



# Results

- Implementing Research Systems can start before electronic clinical systems.
- This implementation preferably can be lead by medical personnel with IT background and can be conducted by them leading to faster analysis, development and evaluation phases.
- Suggested IT knowledge: Systems Analysis, Database design and any Programming language.
- If you've the will and desire you can implement it within one year (even in developing country).
- Integration of research system can result in improving clinical system.





# Recommendations

- We recommend using web based settings, with the advantages of ease of access and maintenance.
- The developed system can be easily applied in the course of management of other chronic diseases.



# Future perspectives

- Integrating bio-banking and translational research.
- Bio-informatics.
- Web-services to talk with other applications.



# The Developers

From the Left:

**-Mohamed Kamal, R.Ph.**

*Clinical Pharmacist*

**-Ahmad Samir, M.D.**

*MSc. Ophthalmology*

**-Mohamed Sabry, M.D.**

*MSc. Clinical Research*





# Other Team Members

- **Dr. Sherif Abouelnaga, M.D.**

*Pediatric Oncologist*

- **Hatem Hosni, M.D., M.Sc**

*Cardio-Thoracic Surgeon*

- **Omneya Hassanain, BCOP**

*MSc. Clinical Pharmacy*





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**THANK YOU**