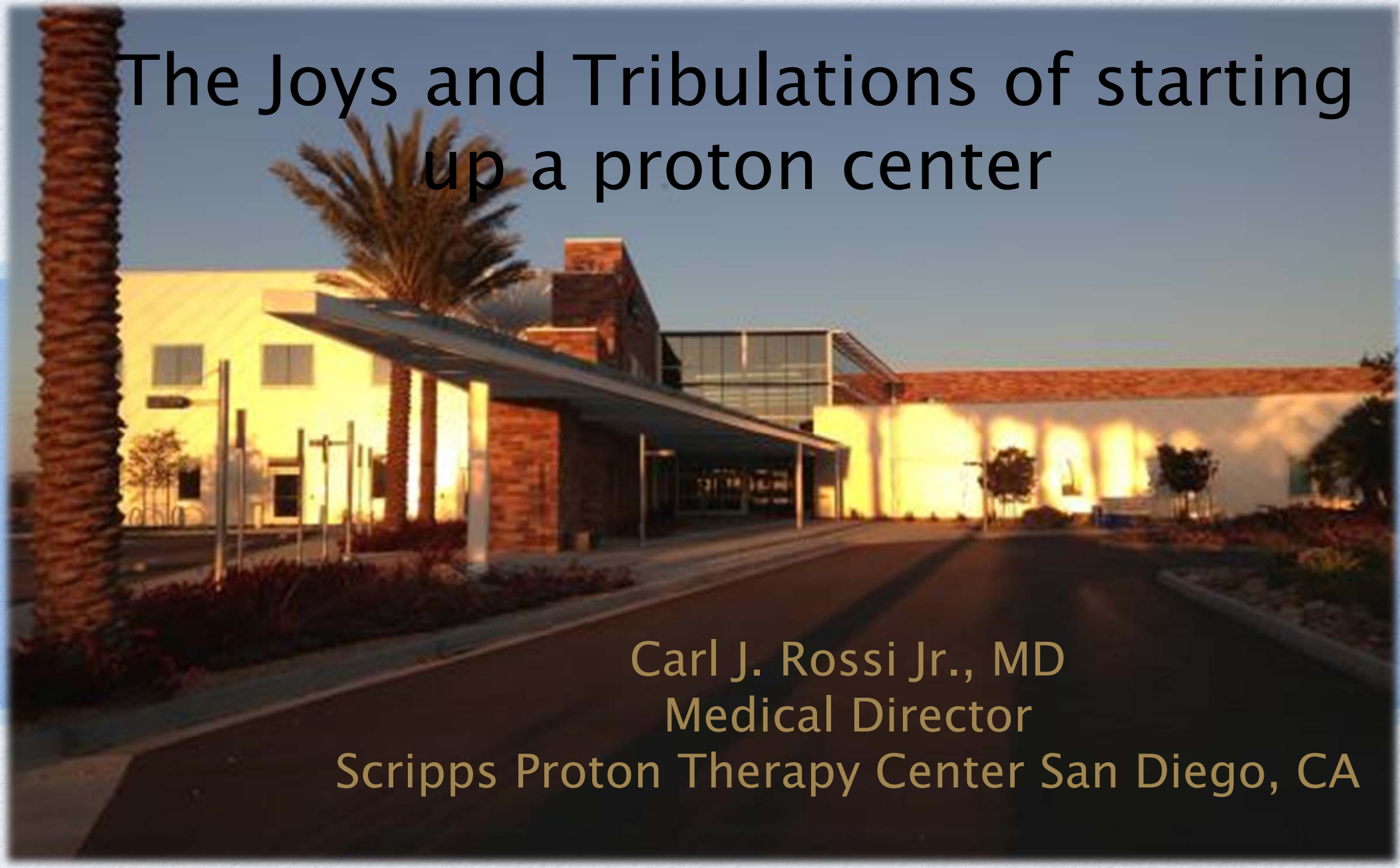

The Joys and Tribulations of starting up a proton center

Carl J. Rossi Jr., MD
Medical Director
Scripps Proton Therapy Center San Diego, CA

Overarching Themes

- Experience helps-but every project has its own unique twists and issues-you have got to be flexible and malleable.
- Do not underestimate the complexity hardware-and software-installation and integration.
- It’s easy to get discouraged but remember that others have been there now before you

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“Now that the money has run out we must start to think!”
-Jackie Fisher, FADM RN, 1904

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Sir John Arburthnot Fisher

- FADM, Royal Navy
- Was tasked with guiding the RN thru a period of great technological change:
  - Turbine Propulsion (=high fleet speeds)
  - Rapid Advances in Gunnery (=need to engage targets at long ranges)
  - Integration of Wireless (into a fleet which relied on signal methods unchanged from Nelson at Trafalgar in 1805).
  - He accomplished all of this, and his success was largely responsigle for RN success in WWI.

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Initial Operation and Ramp-Up

- Lots of interlocking parts!
- Lots of unknowns!
- Lots of expectations!
- Lots of headaches:)
- The buck stops here.....

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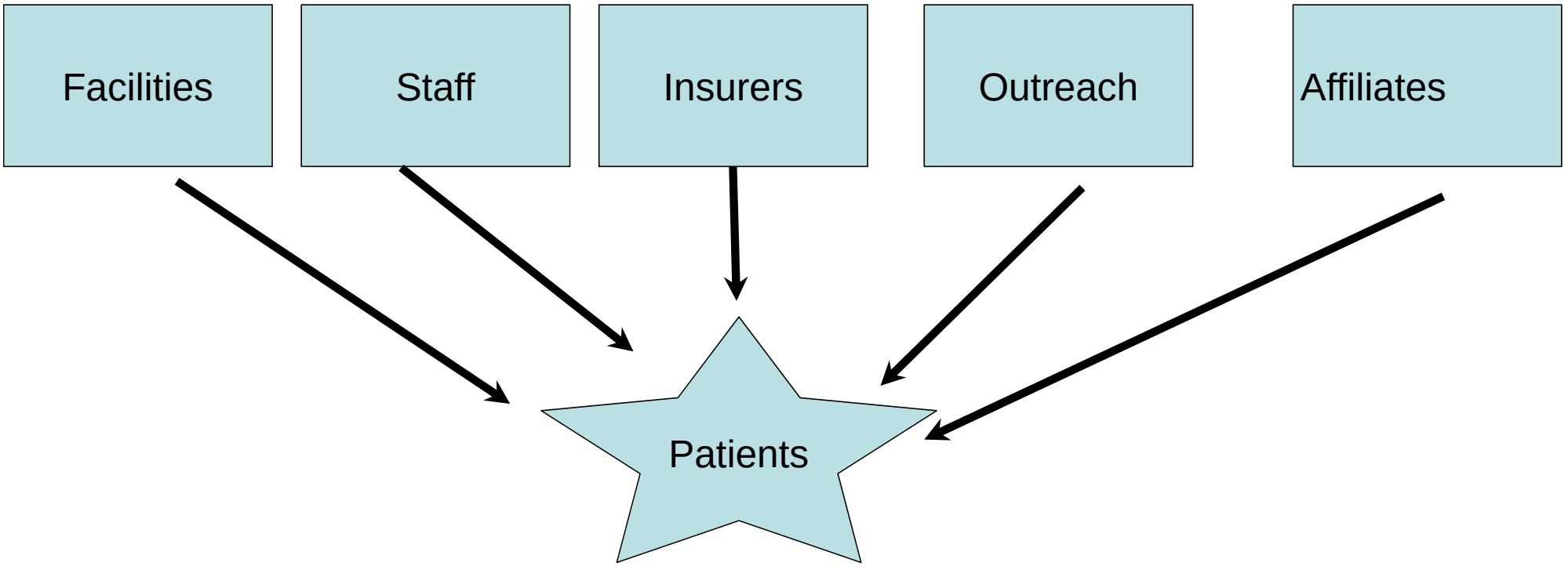
Ramp-Up Overview

Goal-First Patients Treated 6/03/13



Reality-First patient treated 02/12/14

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Facilities

- When operational, beam time available for clinical work (including QA) is primary limiting factor:
  - Determines total # of daily treatments
  - Determines case type (simple vs complex, adults vs peds)
  - Other unknowns in treatment system (e.g., how do you manage patient/target motion) also will limit case types.
  - All this information is critical in determining goals for patient numbers as facility comes on-line.

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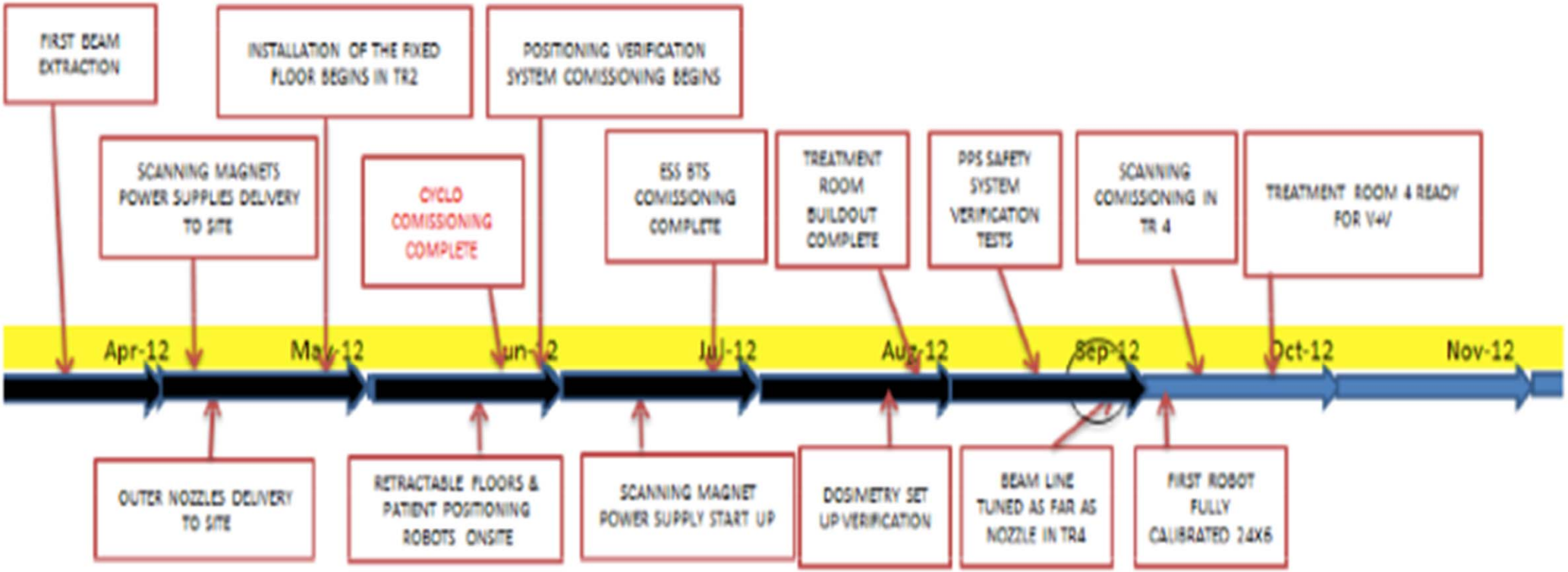
Varian – Project Timeline



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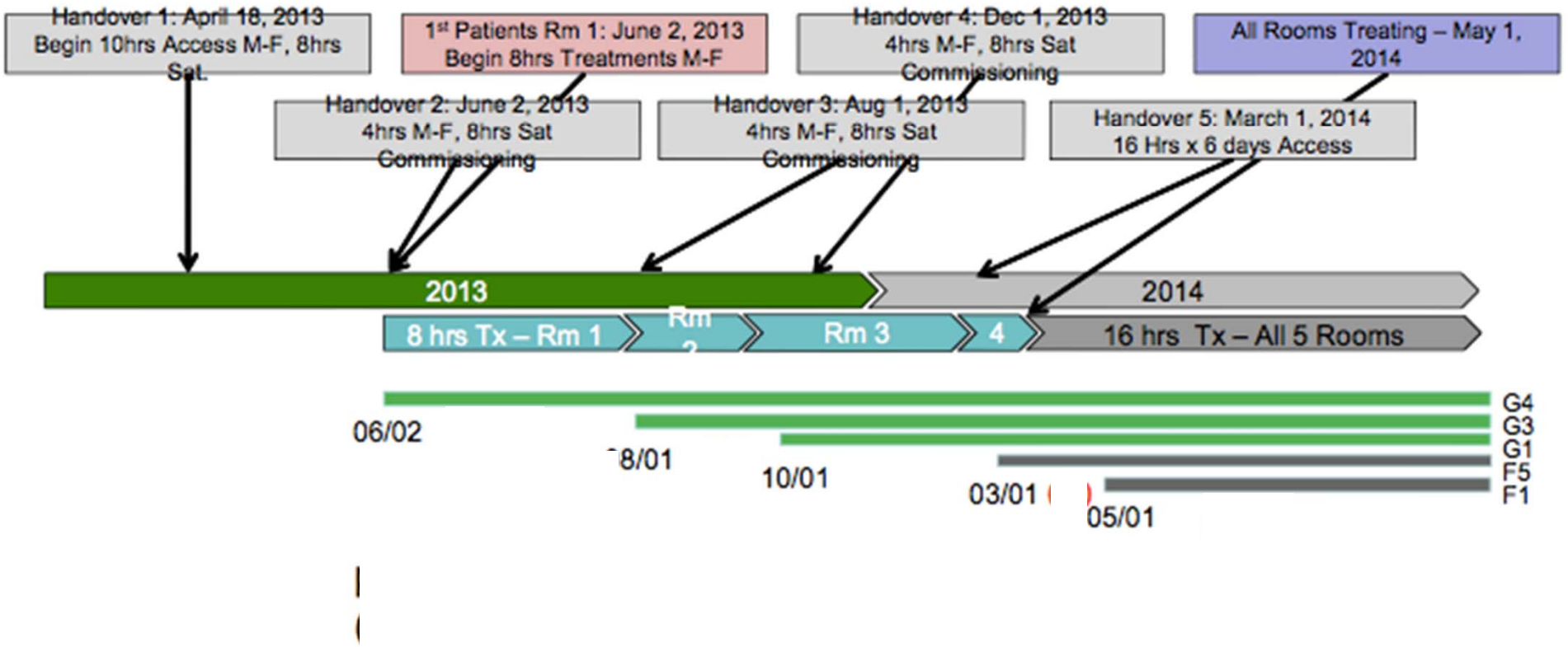
Timeline, Room Availability, Tx Capacity



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Reality…

- Construction commenced 8/2010.
- Cyclotron delivered 10/28/2011.
- First Beam out of Cyclotron 02/12.
- Software Development-took longer than expected…..so commissioning not completed until 10/13.
- 510K Data Submitted 10/13
- US Government Sequester delays FDA…..
- 510K received late January 2013.
- =8 months later than initial timeline.

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Staffing

- Physics staff is most critical to assemble early as they have major role in preparing facility for operation.
- MD's are most expensive so delaying hiring as long as is reasonably possible makes financial sense. Also suggest bringing additional staff on slowly, use experienced and willing "fill-ins", if available.
- Even though starting out with one tx shift, consider hiring RTT's for two shifts.
- Don't forget imaging tecs!

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Recruitment / Staffing

Position Title	Pre-Opening Hires	July 2012 Hires	Sept 2012 Hires	Oct 2012 Hires	Nov 2012 Hires	Dec 2012 Hires	Jan 2013 Hires	March 2013 Hires	April 2013 Hires	June 2013 Hires	Oct 2013 Hires	Total FTEs
Medical Director	1.0											1.0
Physicians							4.0					4.0
Chief Medical Physicist	1.0											1.0
Asst. VP	1.0											1.0
Project Manager	1.0											1.0
Radiation Physicists - PhD		1.0						1.0				2.0
Radiation Physicists - Mid		1.0						1.0				2.0
Radiation Physicists - Jr.		2.0						1.0				3.0
Radiation Physicist - MRI						1.0						1.0
Physics Assistants							2.0				1.0	3.0
Physics- Research Scientist							1.0					1.0
Application System Administrator				1.0								1.0
Supv, Dosimetrist		1.0										1.0
Dosimetrist							5.0					5.0
Supv, Radiation Therapy (RTT)				1.0								1.0
Radiation Therapist (TX & CT/Sim)								8.0		2.0	5.0	15.0
Mgr, Patient Care			1.0									1.0
Mgr, Business Operations					1.0							1.0
RN Case Manager								3.0			2.0	5.0
Registered Nurse							2.0					2.0
RN- Specialized Services (Peds)										1.0		1.0
Anesthesia Tech										1.0		1.0
Medical Assistant								1.0			1.0	2.0
Radiology Assistant (RTT Asst)									3.0	1.0	1.0	5.0
MRI Tech								1.0				1.0
Nuc Med Tech								1.0			1.0	2.0
Executive Assistant I	1.0										1.0	2.0
PSR II (Scheduler / Registration)								8.0			1.0	9.0
Health Info Tech/Transcription								1.0				1.0
Sr Financial Analyst		1.0										1.0
Social Worker Clinician										1.0		1.0
Registered Dietician										1.0		1.0
Research Nurse										1.0		1.0
Clinical Coordinator (Research)										1.0		1.0
Concierge								1.0				1.0
Totals	**5.0**	**6.0**	**1.0**	**2.0**	**1.0**	**1.0**	**14.0**	**27.0**	**3.0**	**9.0**	**13.0**	**82.0**

10/15/2012

Hired
Off Posting
Posted

Staff Positions Through 2013

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Physician Staffing and Ramp-Up

- Keep in lean.....at SPTCramp-up plan called for only two rooms (and 10 hours of treatment time) for ~60 days. Don't need 10 MD's to treat 20 patients!
- Since bringing on new staff can take several months, if possible have people on stand-by who can temporarily fill in if case numbers rise rapidly. At SPTC we did this via arrangement with existing staff at SRTC.

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Case Types During Ramp-Up

- Complexity inversely impacts thru-put.
- New Technology + New Facility + New Staff=penchant for disaster? So……keep it simple at first! Coordinate with Physics to decide which types of cases to start with:
  - Prostate
  - CNS
  - Extremities
  - Central Lung (no motion)
  - Mets! This is counter-intuitive but excellent intro to treating challenging cases.

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Cases to approach with caution

- Peds-Primary CNS can be treated early, CSI perhaps not!
  - –Recognize potential effects of involved peds cases on thruput, but also recognize potential adverse effects of delaying peds accessability to referring docs.
  - –Highly mobile targets.
  - –Radiosurgery.

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Insurers

- Meetings with commercial payers have to begin several months prior and should be integrated into contracting cycle.
- California Medicare Intermediary (Palmetto) was contacted 2/12 (24months prior to first patient tx) and I was verbally assured “We’re paying Loma Linda, why wouldn’t we pay you”?
- Scripps Contracting began meeting with commercial payers and incorporating PBT coverage into contracts as they come up for renewal, typically 12-24 months prior to facility opening.

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Outreach-Physicians

- Most referring docs (particularly PMD's) couldn't tell a proton from a peach-they need to be educated.
  - –Grand Rounds.
  - –Direct Meetings with medical groups (Scripps Coastal).
  - –Don't limit outreach to MD's! As more MD extenders are employed, their importance in directing referrals grows commensurately.
  - –Timing? Never too early to start-ramp up frequency of meetings as center opening nears.
  - –Outreach=marketing

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Outreach-Media

- Need to plan concerted effort to promote facility on a graduated basis. No point in starting too early, when you can't treat.
- Scripps plan called for marketing effort to begin in Fall 2013, but graduated increase thru and after opening.
  - –Billboards/Banners --Website
  - –Service Clubs
  - –Open Houses
  - –Inclusion in newsletters
  - –Radio/Television Ads

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Affiliated Physicians?

- Scripps system currently treats ~2,500 patients/year. PTC goal is ~1,000 patients/year. So.....where will the rest come from? Can't ramp-up without patients:)
- One possibility is to recruit other physician groups to treat patients at SPTC.
- This required two components:
  - Legal method to allow non Scripps MD's to treat at SPTC.
  - Proctoring for outside MD's.

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Affiliated MD's

- SPTC established affiliation with Rady Children's Hospital (largest peds hospitalin CA) to treat appropriate patients with protons.
- UCSD clinicians are full members of SPTC staff, treat their patents at SPTC. UCSD residents rotate thru SPTC.
- Large private practice group has also expressed strong interest in treating patients at SPTC.

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SPTC Ramp-up

- Three full-time staff (including me) on site in early 2013. Why so early? Outreach, protocols, tumor boards.
- I started seeing GU consults (because they could “wait) 4 months prior to go-live date.
- Goal was to have ~20-40 patients ready to start treatment when we got our first rooms.
- Peds will be offered from outset, but initially with very limited #’s and types of cases. First teen May 2014, first anesthesia July 2014.

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SPTC Ramp-Up

- As facility capabilities increased thru 2014, hiring occured based on needs-this was and is a dynamic process.
- By late 2014 we were able to offer treatment of more complex, esoteric cases.
- RPC accreditation in late 2014=opens door for participation in clinical trials-you have to plan in advance for this!

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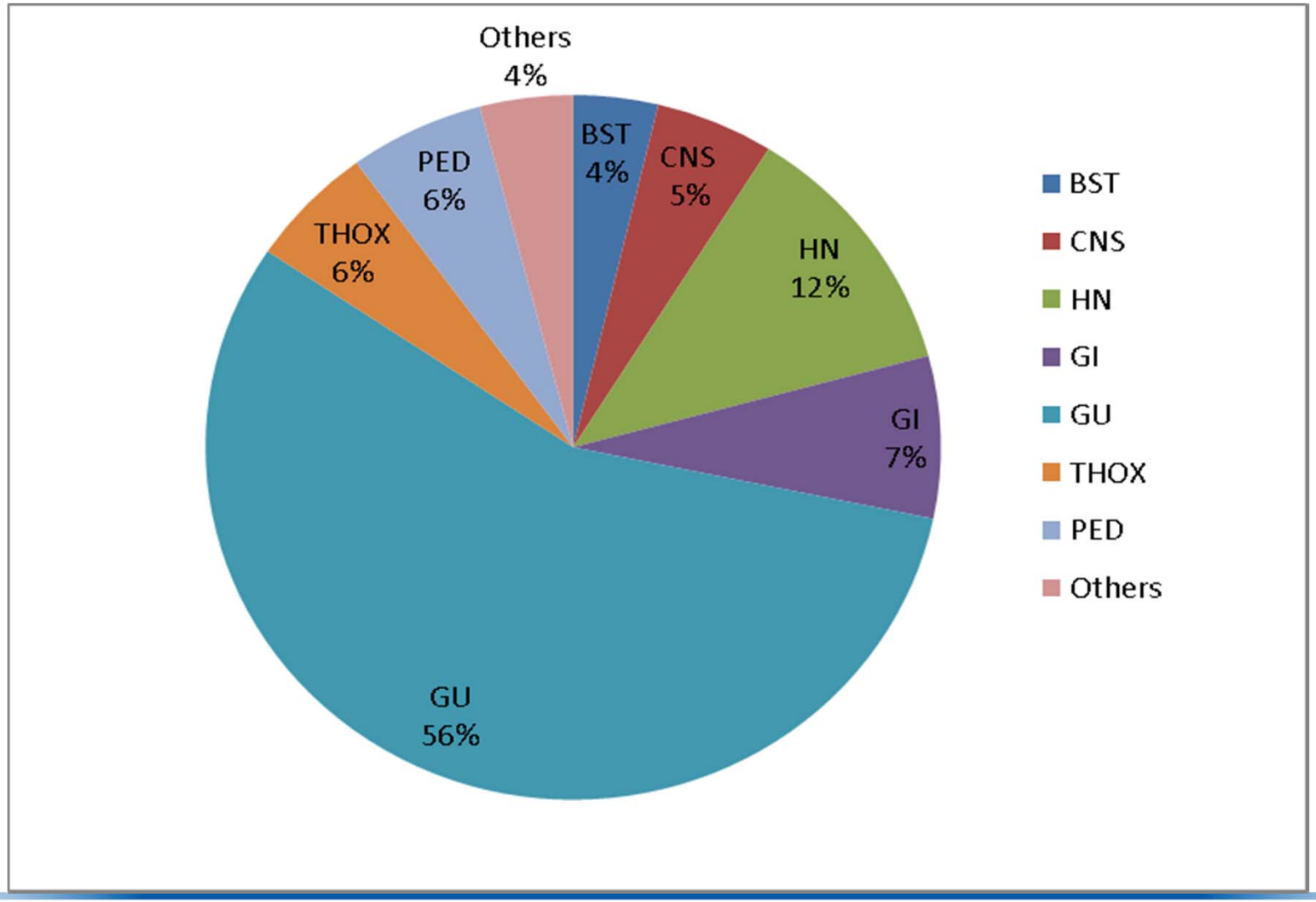
Statistics through first 270 patients (Jan, 2015)



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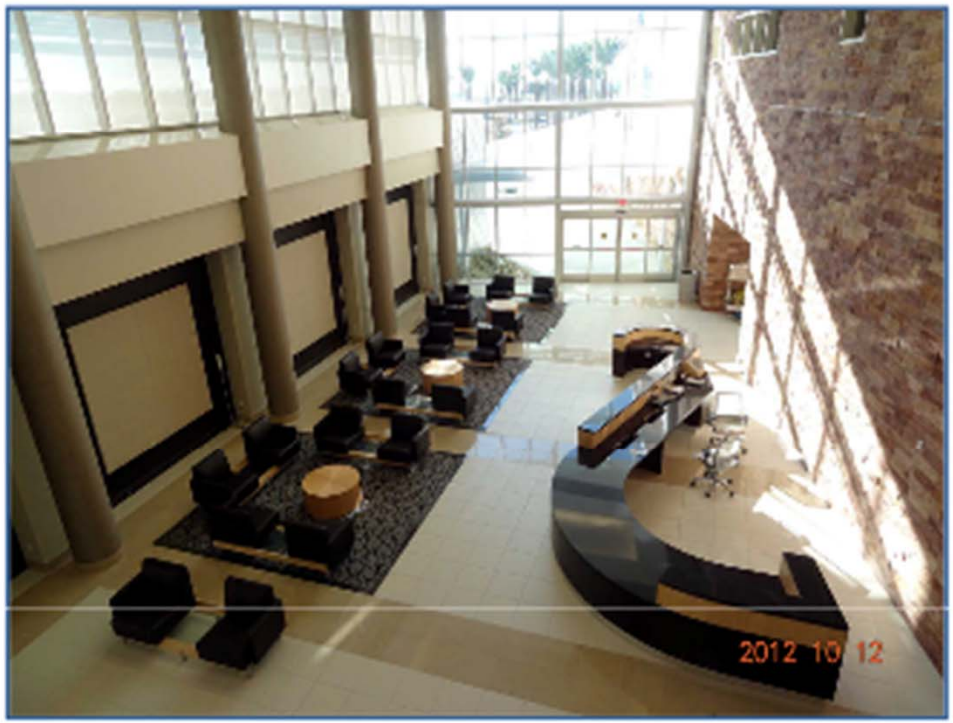

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