Working with HIT Vendors

What’s the Secret?

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Working with Vendors: Overview

- Get in the (right) door
- Find a hook
- You’re the expert, not the vendor
- Protect your interests
- Protect your patients
First, a Word from Our Sponsor…

- Disclaimer: No vendor affiliations at this time
  - Not necessarily opposed to it, but I’ve got “issues”

- Some street cred:
  - NLM Informatics Fellow (industrial process models for CDS)
  - Designed early commercial eRx system w/ robust CDS
  - At McKesson during early commercialization of Vanderbilt CPOE
  - RxHub (Surescripts); neutral utility servicing dozens of vendors
  - Directed a CMS eRx Pilot; worked w/ vendors on rapid development and testing of new features
  - CMO at Eclipsys (until July ‘08); often in middle of issues covered here
Get in the (Right) Door

- **Know your organization**
  - You (may) need a sponsor and/or guide
  - CMIO (if you have one) is the best place to start
  - CIO, CMO, CNO, Quality/Safety Director

- **Know your vendor**
  - S&M vs. Services vs. Development
  - Account Manager typically bridges all three and may be best guide
  - Vendor org structure (Who makes resource allocation and feature prioritization decisions? How are those decisions made?)

- **Understand existing channels**
  - Enhancements vs. Defects
  - Working through vs. around the usual channels
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Find a Hook

- Product differentiation that will help them sell more core
  - May even be something on their radar that just haven’t gotten to yet
- New module development that can be sold as add-on
- Oh, yeah, it may be the “right thing” to do…
- Know the contract (and relationship)
  - Are you their most important client? (or just a fly in their ointment?)
  - What application development tools are available (e.g., MLMs, OP) and what permissions to you have to use them?
  - Was the proposed work included in original contract? If not, need to be sensitive to vendor resource requirements and may need new sub-contract for services (unless treated as a defect).
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You’re the Expert, Not the Vendor

- “R&D” is really mostly just “D”
- Many vendors are treading water
  - Lead boot #1: Defect handling
  - Lead boot #2: Certification requirements
- No incentive to allocate “scientific” resources to really cool projects, and may not have the internal expertise anyway
  - Precious little usability innovation from vendors (there’s a reason…)
- But you likely will need their help with learning how to use available tools and may need to contract for custom configuration work or development (guided by your wisdom)
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Protect Your Interests

- “Technology transfer” issues should be addressed up-front
  - Not just an issue between you and the vendor!

- Who owns the innovation?
  - What if it was your design but you contracted vendor to build it?

- Will other clients of the same vendor be able to use it?
  - If it’s any good, they’re gonna want it, badly; who gets paid?

- Is the innovation applicable to users of other HIT products?
  - What’s the market universe for the innovation?
    - Again, better to work this stuff out before you build and test
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Hey-are you thinking what I’m thinking?
State of the Union (Quality Control)

- Some production examples:
  - ASOs, juxtaposition errors, inappropriately flagged abnormalities
  - Not just commercial systems (VA, “home-grown”)

- Surveillance, labeling, recalls, client communications
  - Response (or lack of) to Koppel findings (‘05) is illustrative

- Not immature, early lifecycle or teetering on the brink
  - Market cap of big 5 (Cerner, McK, Siemens, GE, Eclipsys)
  - ~500 hospitals fully CPOE-adopted, many since mid-90s, some on 2\textsuperscript{nd}
  - 500M orders / yr (? Nobody knows)
Best Practices (cGMPs*)

- Design and testing (especially human factors)
- Defect handling
- Surveillance
- Org structure

- Structure \(\rightarrow\) process \(\rightarrow\) outcome
  - Unacceptable variation

Protect Your Patients

- **What are your obligations and exposures?**
  - Scant vendor oversight by FDA + indemnification limits theirs
  - Just because nobody is watching doesn’t mean license to kill

- **What are your internal quality control / safety practices?**
  - Design, defect handling, surveillance, org structure

- **IRB approval?**
  - “QI project”, “not for dissemination” convenient but a bit lame

- **FDA on the verge?**
  - Don’t hold your breath (HIT safety hearings 3/10)
  - MDDS (see if you can figure it out and explain it to me)

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*Miller, Gardner et. al. Recommendations for responsible monitoring and regulation of clinical software systems. JAMIA 1997;4:442-457*
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