



Centralized Subject Monitoring

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November 8, 2004

Department of Health and Human Services

- *Weigh new ideas and promote new solutions to encourage innovation in health care*
- *HHS should consider the development of a key service missing from the critical path of clinical research: Centralized Subject Monitoring*

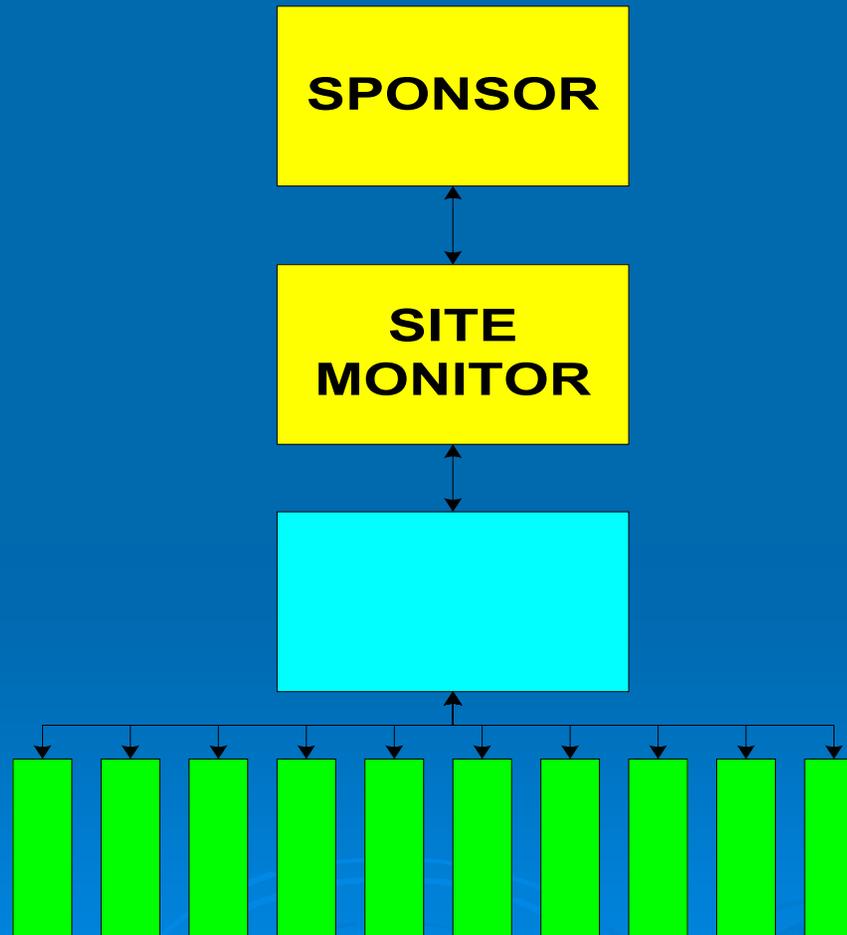
What is Centralized Subject Monitoring

- Simple, innovative solution that has been overlooked
 - New service concept rather than a new technology
 - New evaluation tool for Critical Path Research that addresses issues outlined in the *Critical Path Initiative*
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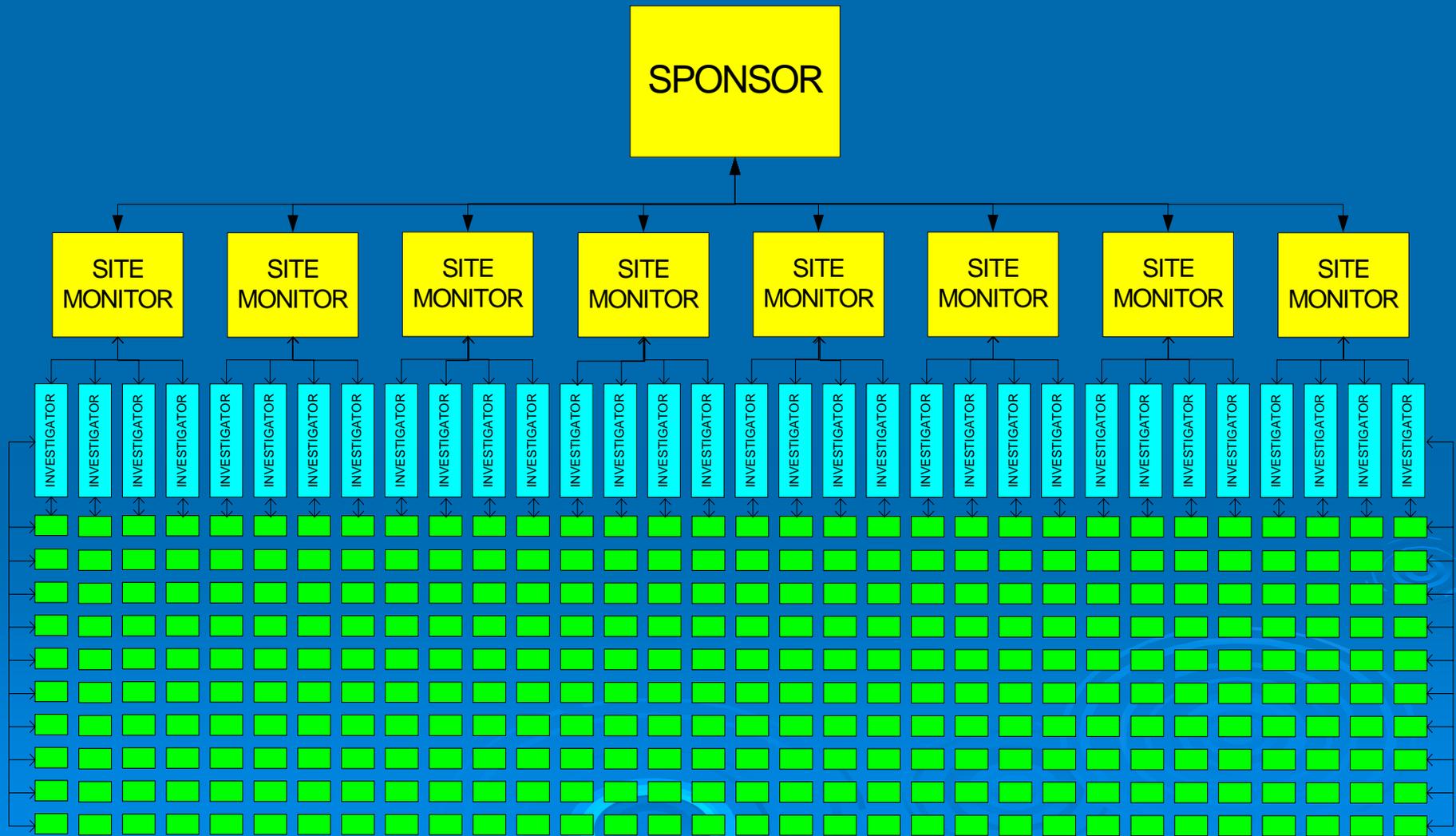
How does Centralized Subject Monitoring work?

- Each subject in a clinical trial is contacted proactively and counseled
- Subjects respond to a series of standard pharmaceutical care questions
- Proactive and reactive support is provided
- Subject information is fed back to the investigator, site monitor, and sponsor, as needed
- Sponsor, site monitor and investigator information provided to subject as needed

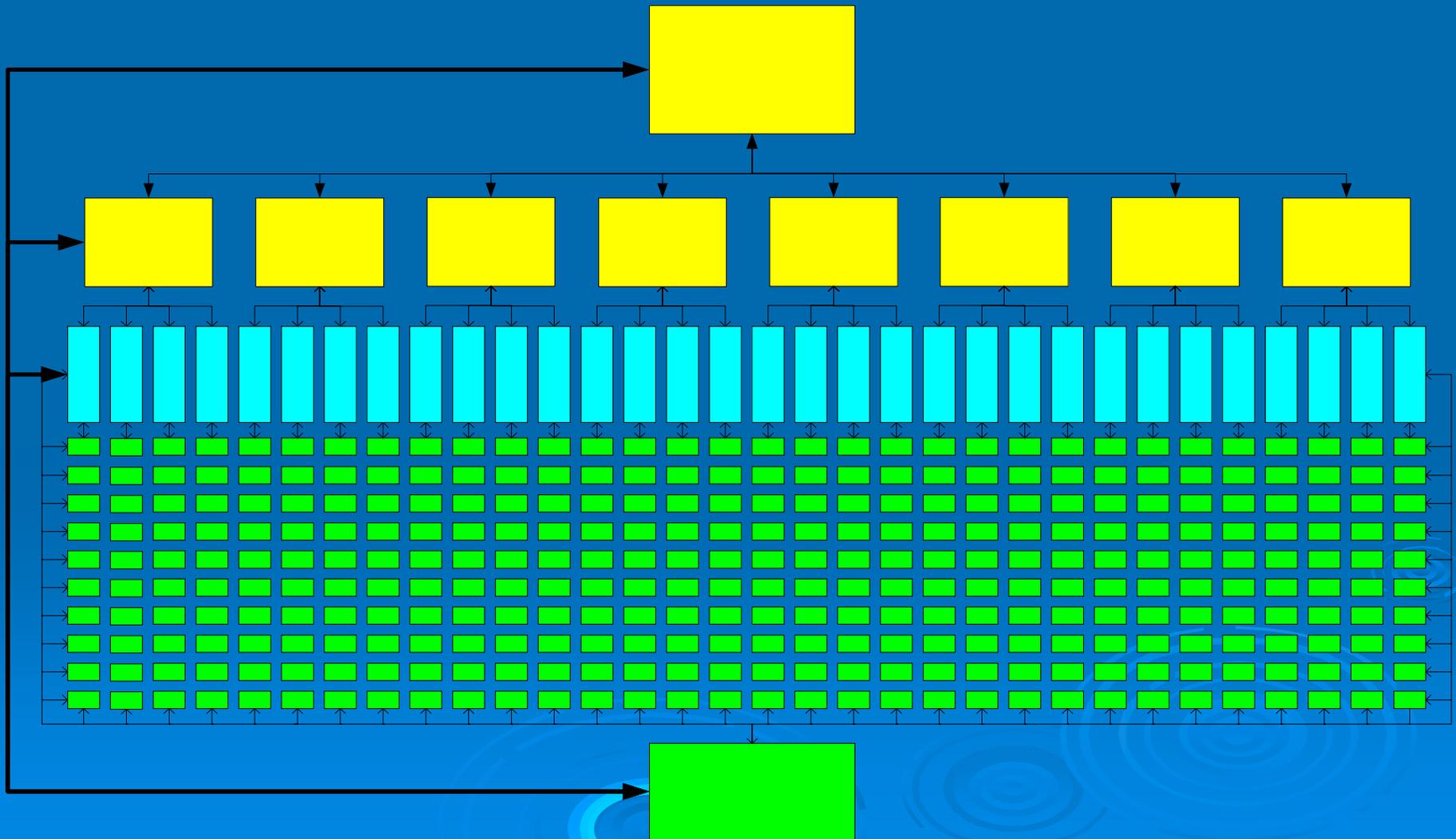
Standard flow of study information



Standard flow of study information



Flow of information with Centralized Subject Monitor



Results from clinical trials using Centralized Subject Monitoring

- Total number of patients counseled 2,244
- Total number of patient contacts 13,326
- Total number of notable interactions 9,199 (69%)
 - Counseling interventions 3,756 (28%)
 - Medication usage 1,555 (12%)
 - Administration of medication 1,212 (9%)
 - Concurrent medications 618 (5%)
 - Proper storage of medication 284 (2%)

Additional results from clinical trials using Centralized Subject Monitoring

Other questions or concerns from subjects:

2,621 (20%)

Adverse events (as self-reported by the
subject):

2,822 (21%)

Impact of utilizing Centralized Subject Monitoring

- Increased subject compliance and accuracy in study medication administration
- Improved pharmaceutical care and disease state management
- Improved clinical data
- Increased identification and reporting of adverse events
- Improved subject well-being

Additional impact of using Centralized Subject Monitoring

- Improved site and site-monitor training
- Improved utilization of existing technologies: electronic patient diaries, RFID tags, IVRS
- Improved clinical evaluation leading to improved protocol and program predictability and efficiency

Key element of Centralized Subject Monitoring: Cognitive Data

- Cognitive data to be evaluated in parallel with quantitative data at end of trial
- Centralized communication and cognitive data utilized to improve patient reported outcomes

What strategies and approaches could HHS implement to accelerate the development and application of new drug technologies?

- HHS to embrace the concept of Centralized Subject Monitoring
- HHS to work with industry to provide incentives and guidance to clinical trial sponsors to utilize and expand upon Subject Monitoring services

How can HHS help its agencies to work together more effectively to speed the development of new drug technologies?

- Suggest HHS create a focus group of industry and agency members to study the implications of Centralized Subject Monitoring
 - Focus group to address agency benefits and obstacles
 - All agencies to participate