

# An Information Architecture for Clinical Research: *Leveraging Technology to Speed Discovery*

► ***Architecture?***

*Why Here?*

*Why Now?*

*Architecture...*

*Where we are*

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N.I.H. Clinical Center



**Architecture?**

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**Architecture?**

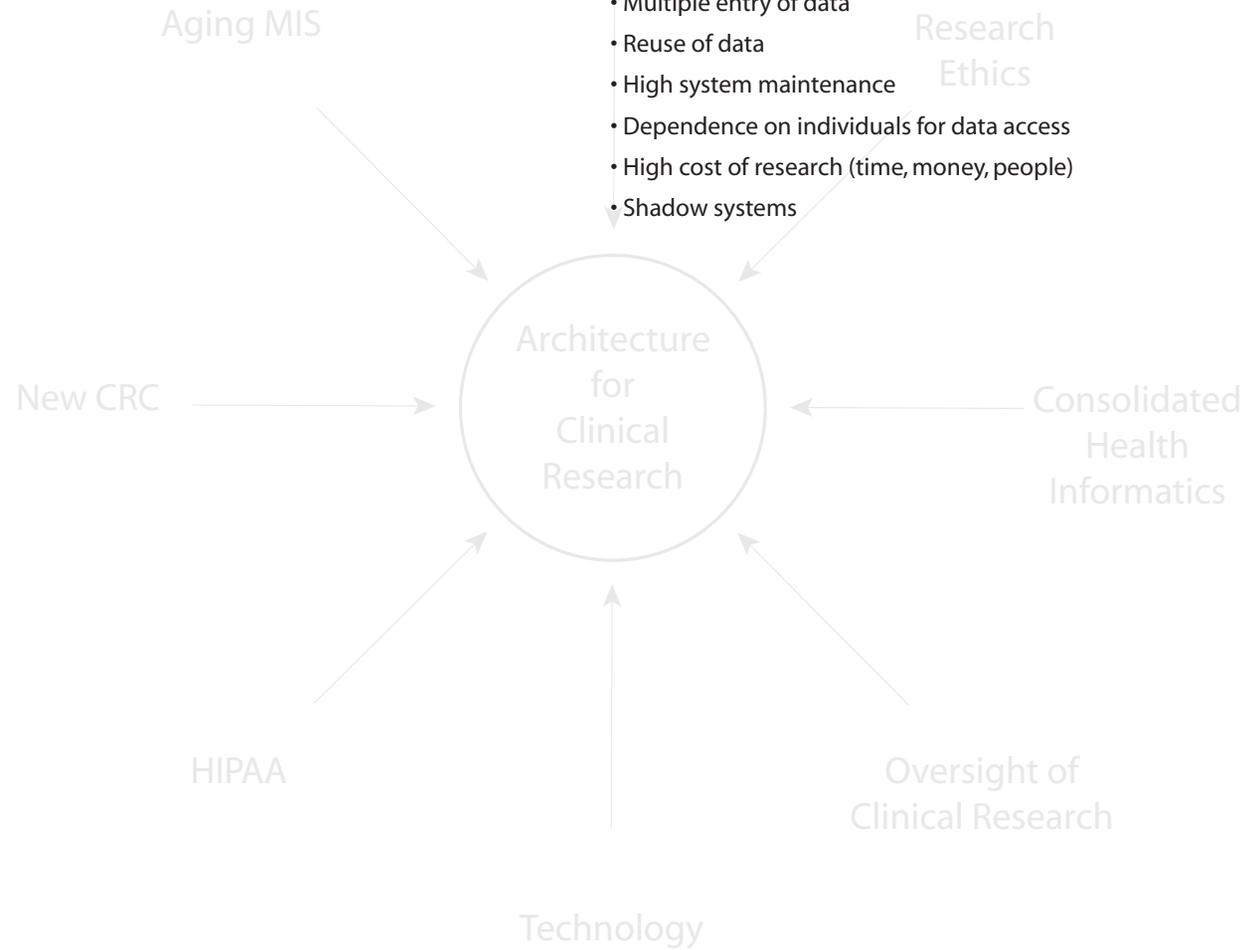
**Why Here?  
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## Scientific Opportunity

- Personal experience
- Multiple entry of data
- Reuse of data
- High system maintenance
- Dependence on individuals for data access
- High cost of research (time, money, people)
- Shadow systems





**Architecture?**

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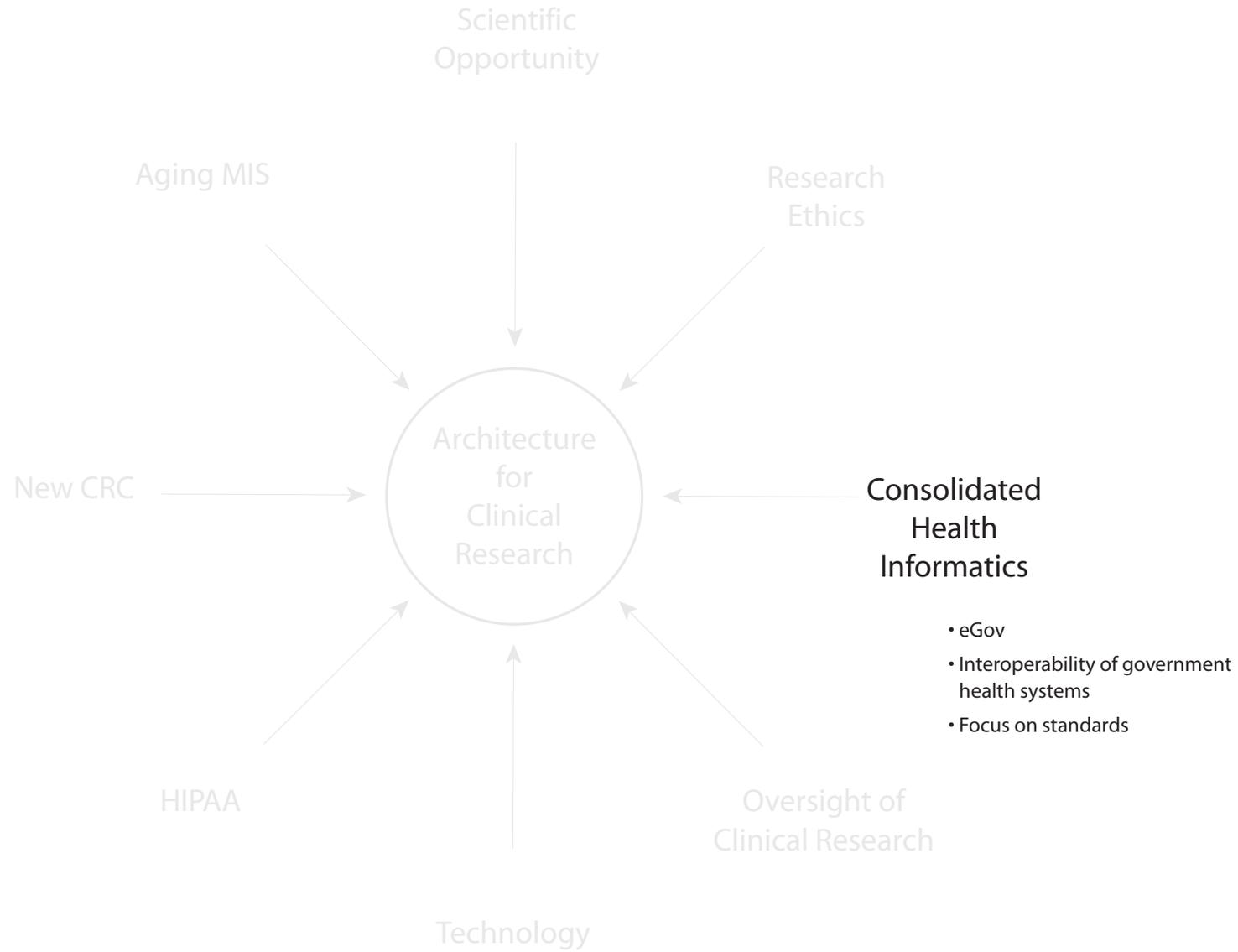


**Architecture?**

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- Regulatory spiral
- Burden of oversight falls on PIs, IRBs, Institutions
- Hopkins suspension NOT for death of normal volunteer, but for inadequate and underresourced review process



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### Technology

- Rising expectations (internet/WWW)
- Falling costs
- Relational databases
- Gigabyte storage

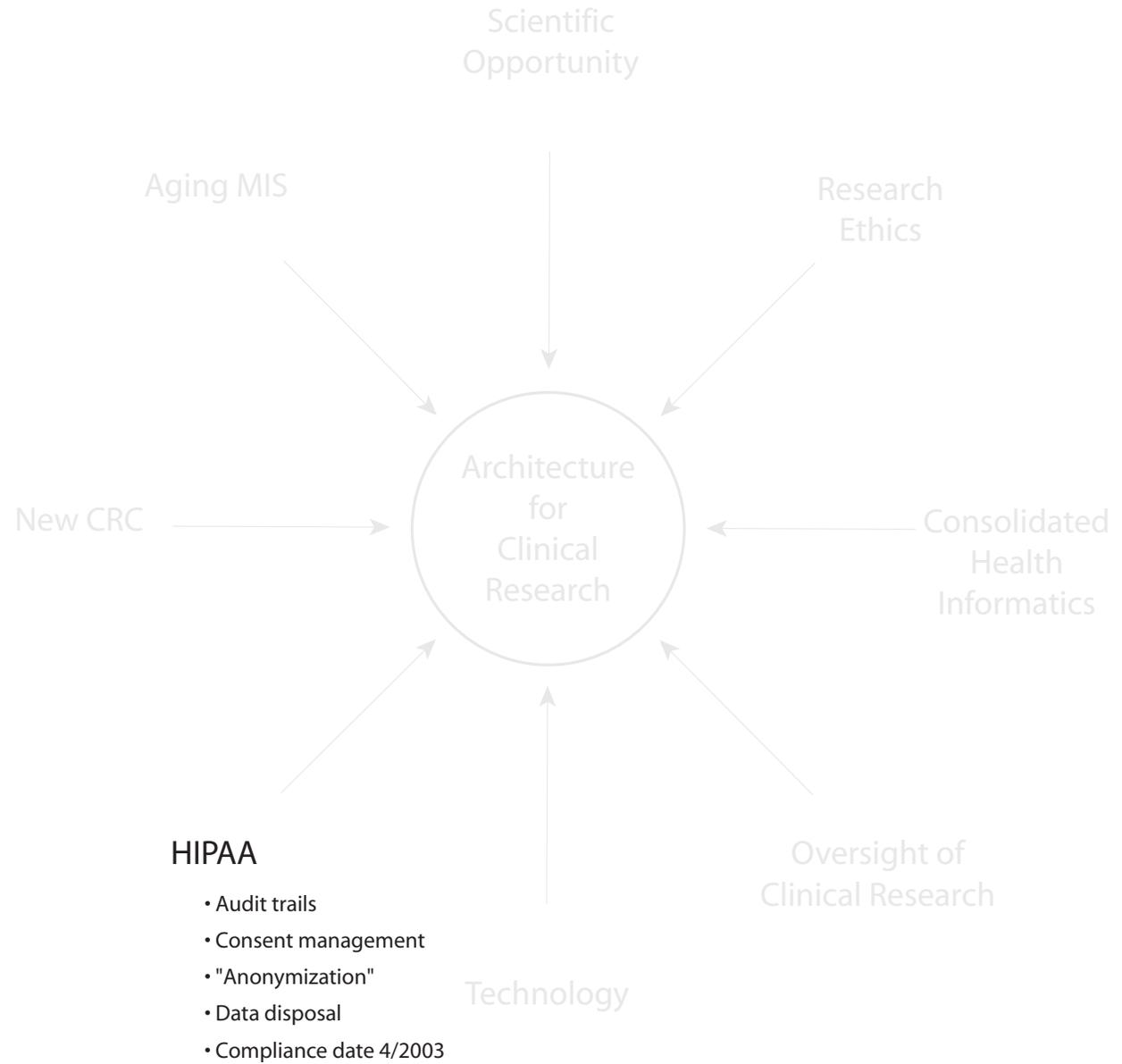


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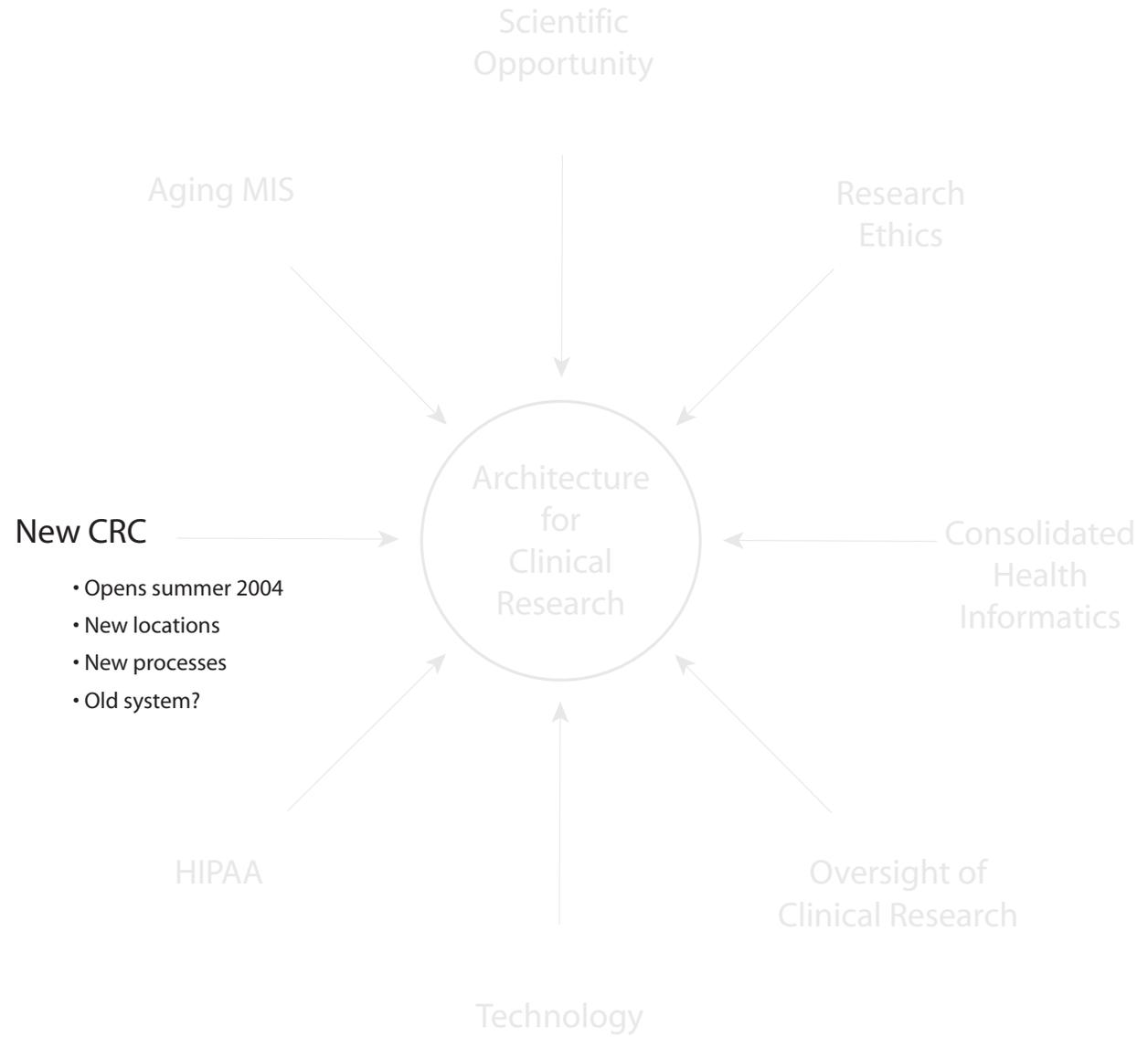


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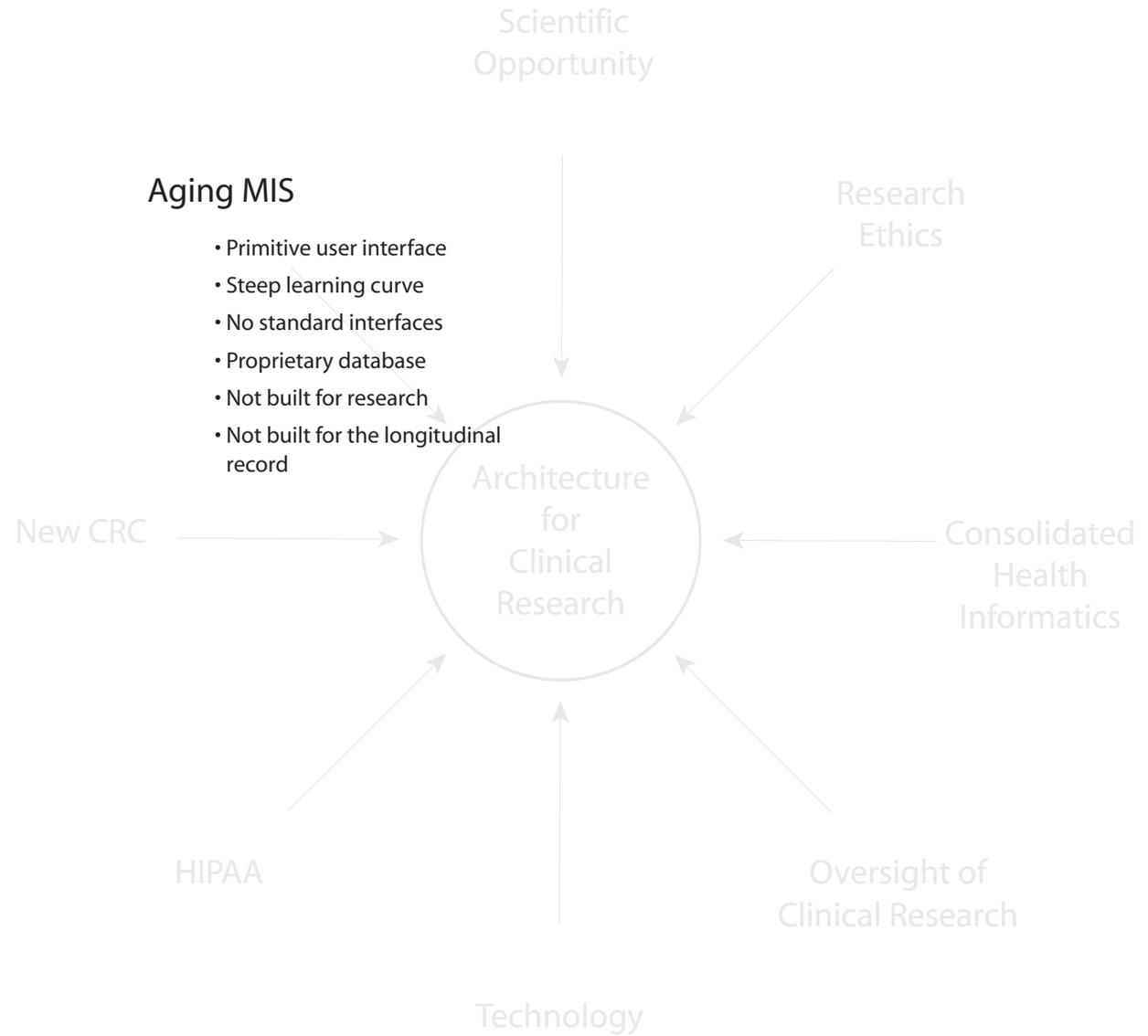


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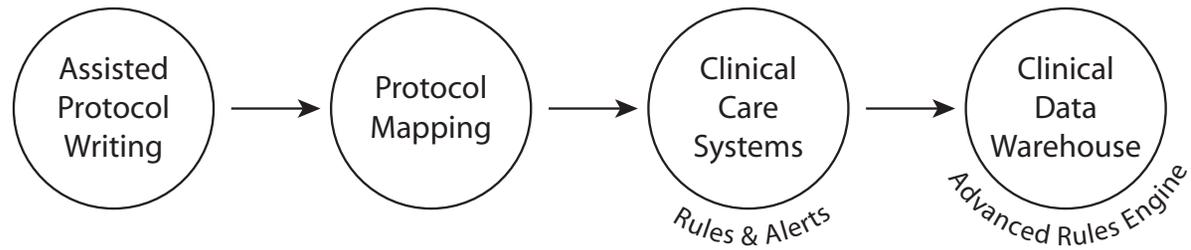
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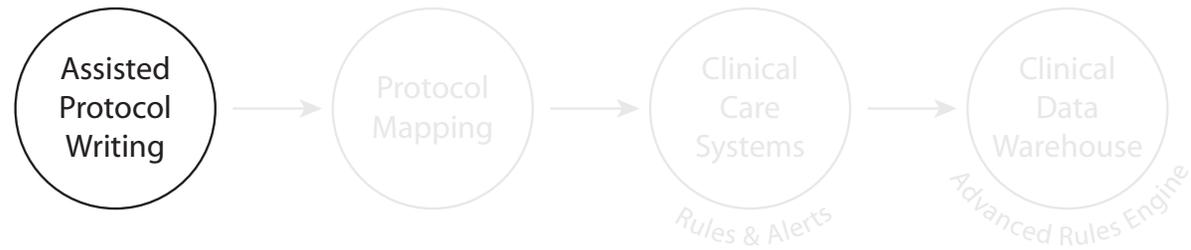
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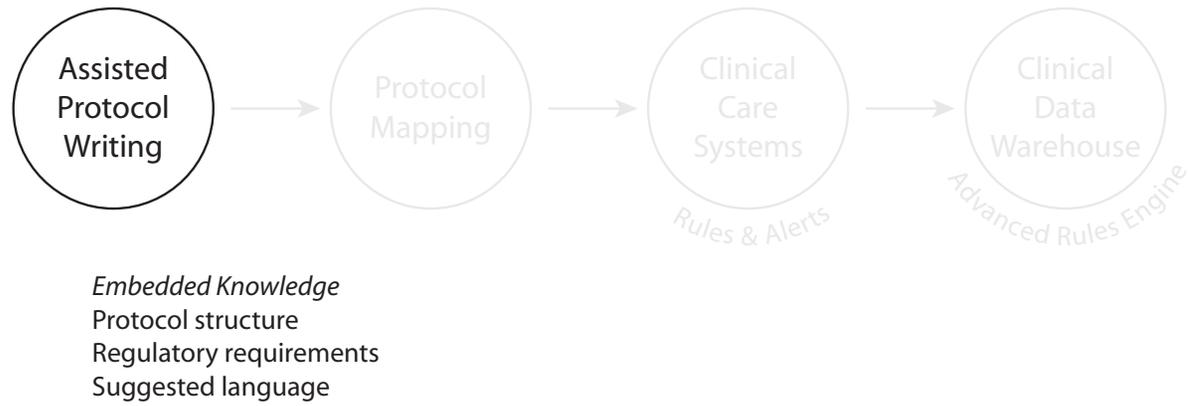
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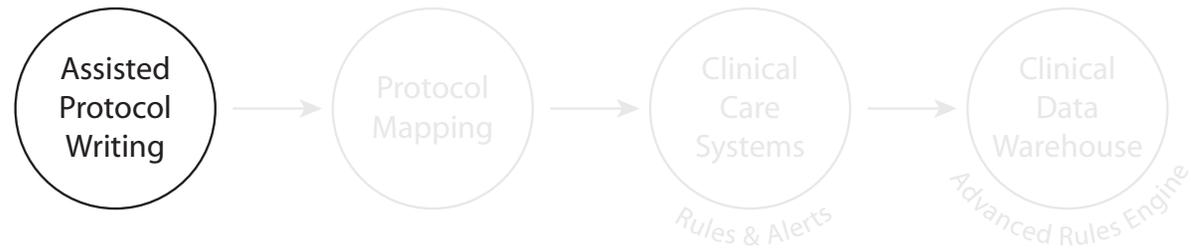
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*Outputs*

- inclusion criteria
- exclusion criteria
- protocol synopsis
- research care plan
- adverse event reporting plan
- protocol



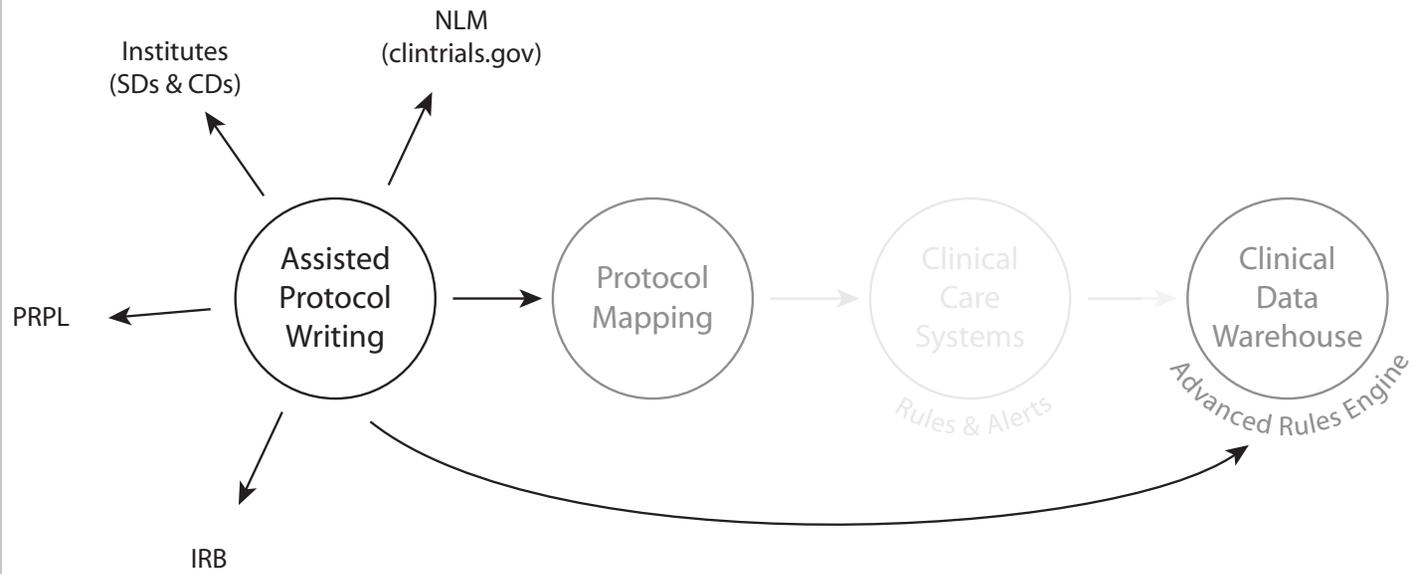
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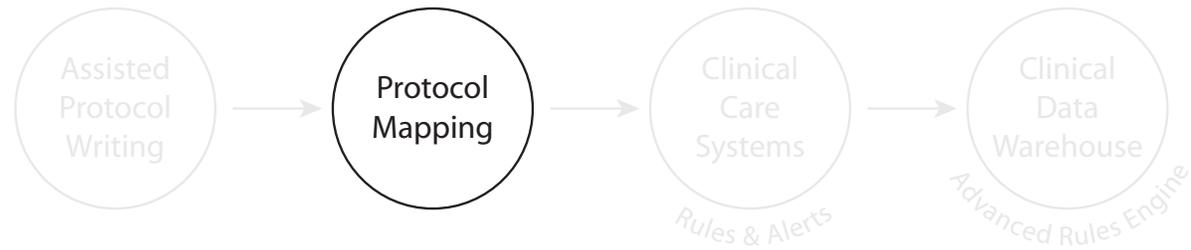
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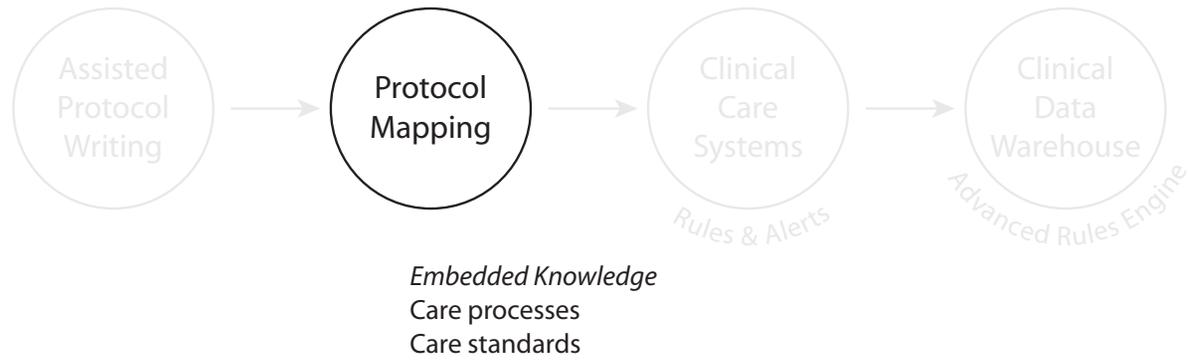
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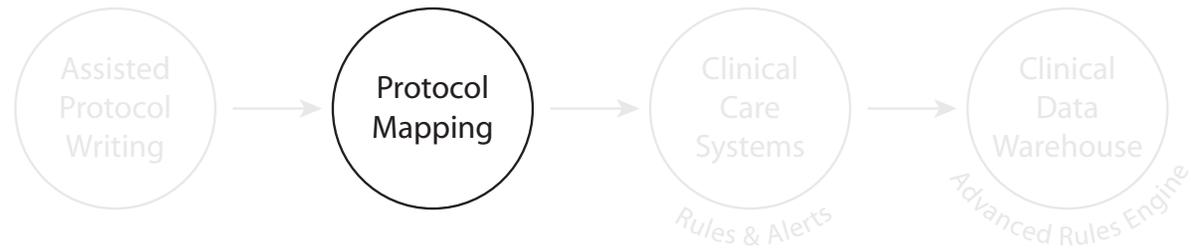
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*Outputs*

Detailed care plan

Data collection plan

Protocol context for results/documentation

Projected activity volumes

Total dose (x-ray & blood)

Patient calendar



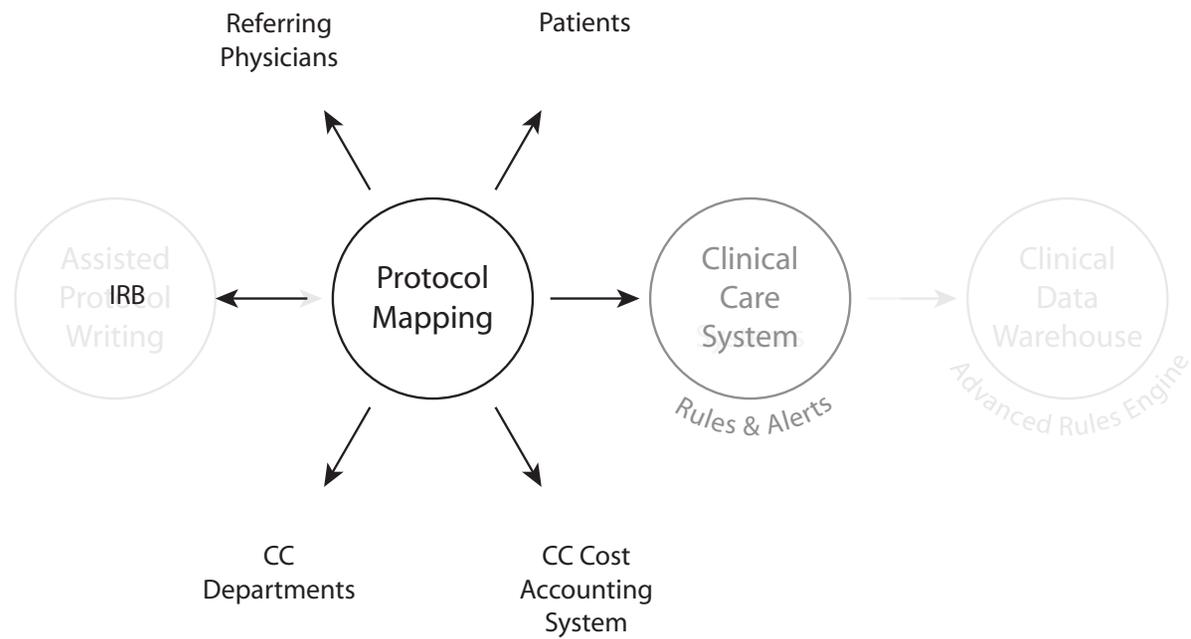
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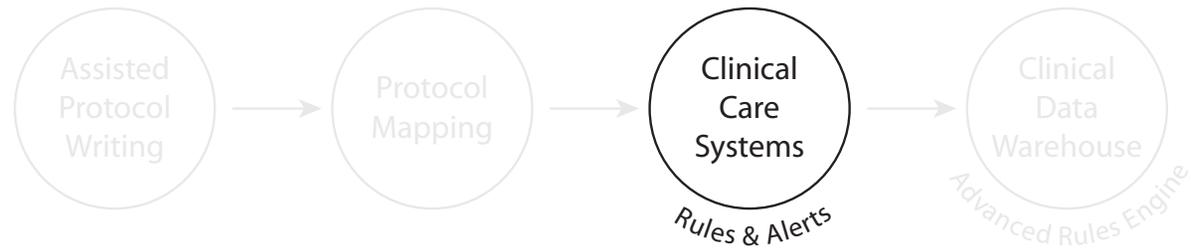
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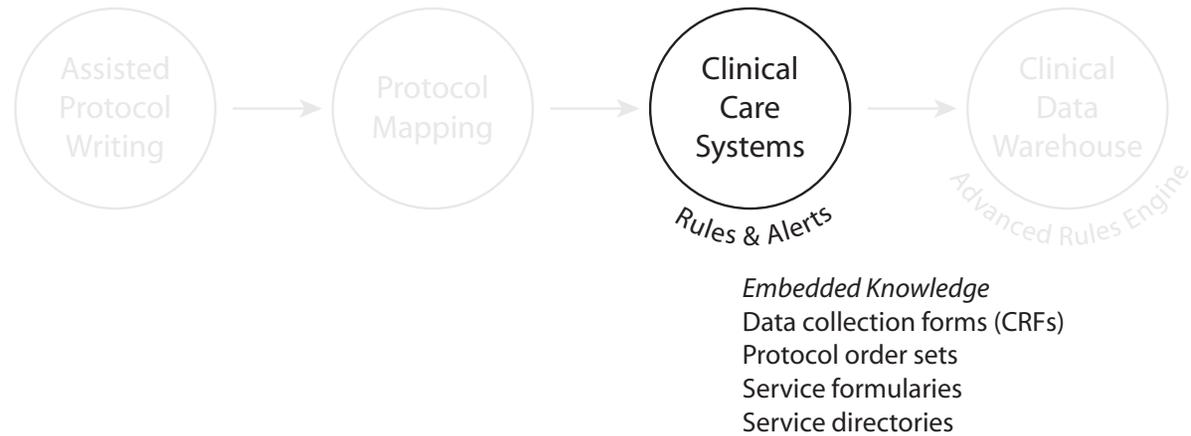
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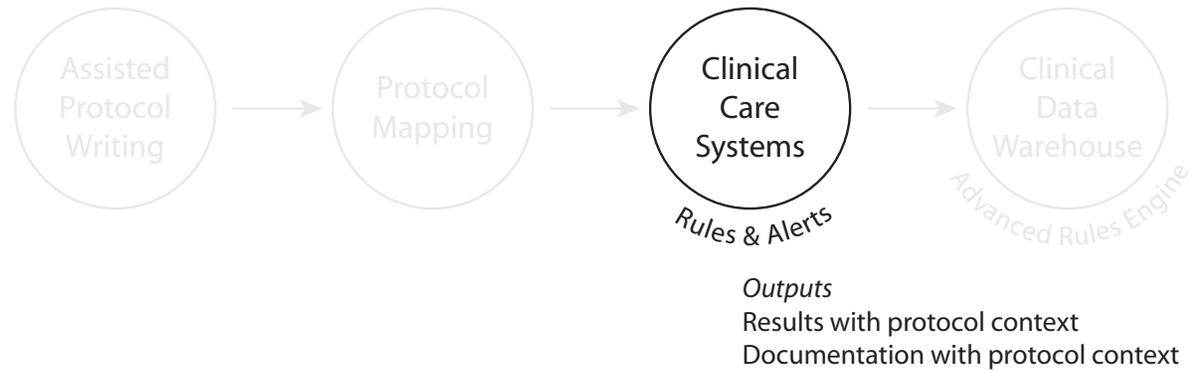
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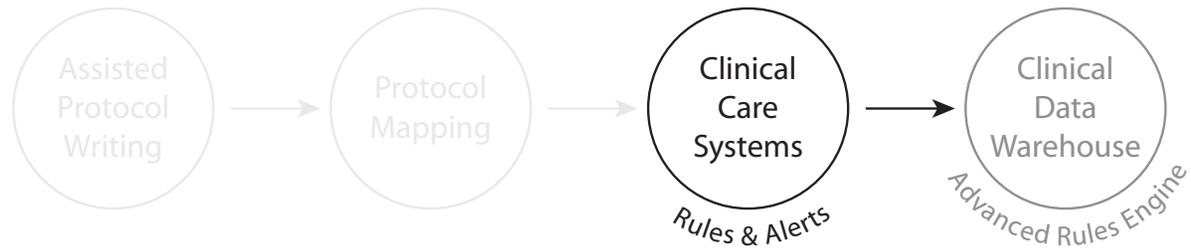
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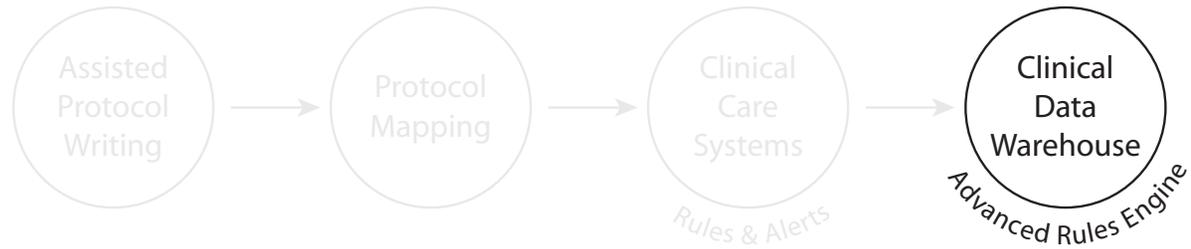
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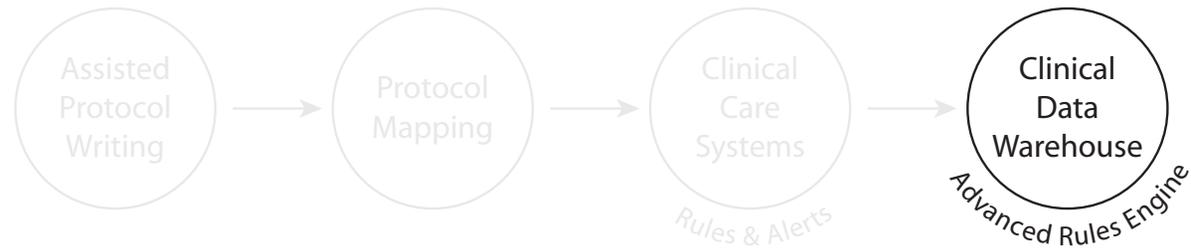
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*Embedded Knowledge*

Adverse event detection rules

Adverse event reporting rules

Event cluster detection rules

Event cluster reporting rules

Regulatory reporting rules

DSMC reporting rules



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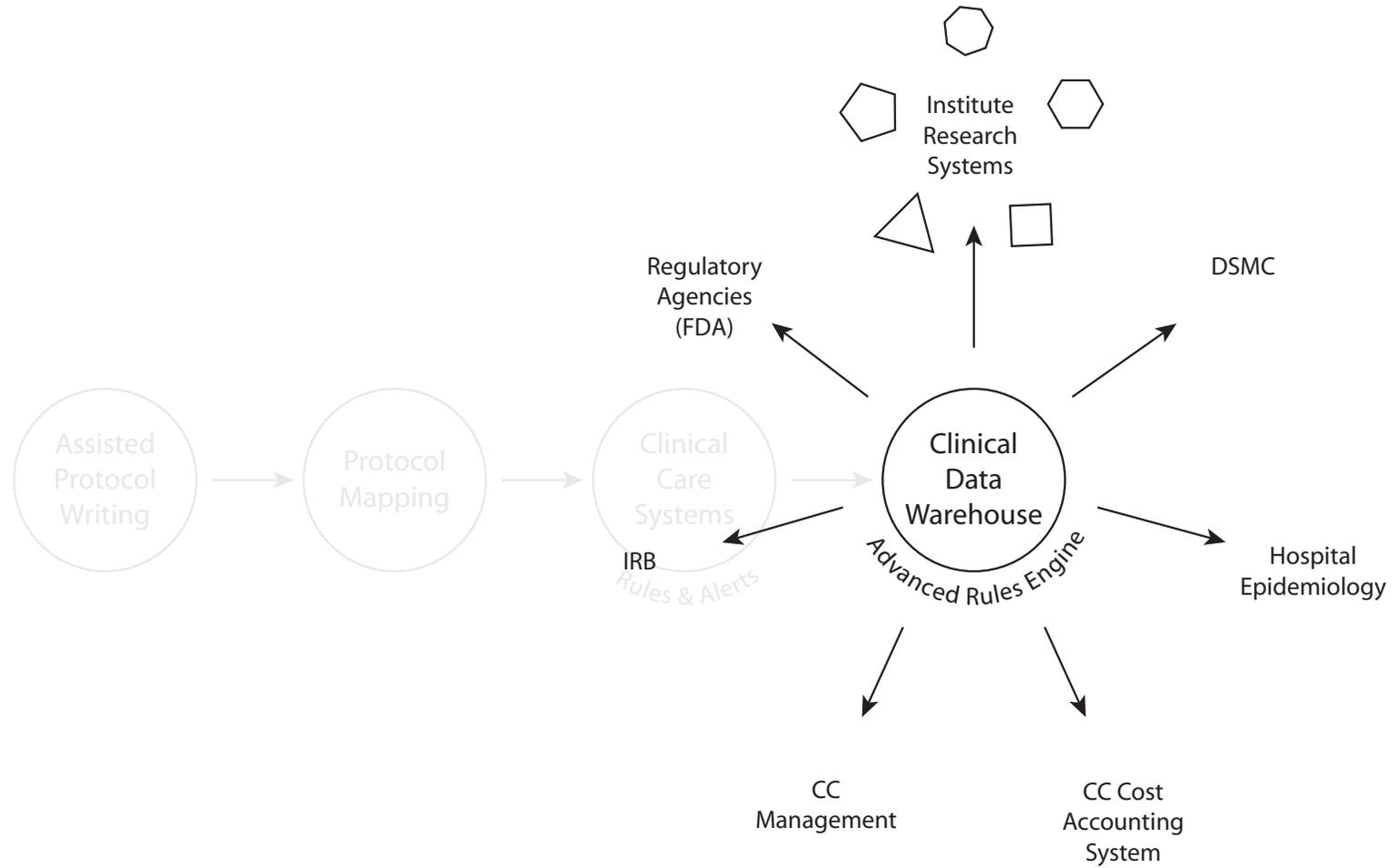
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C R I S

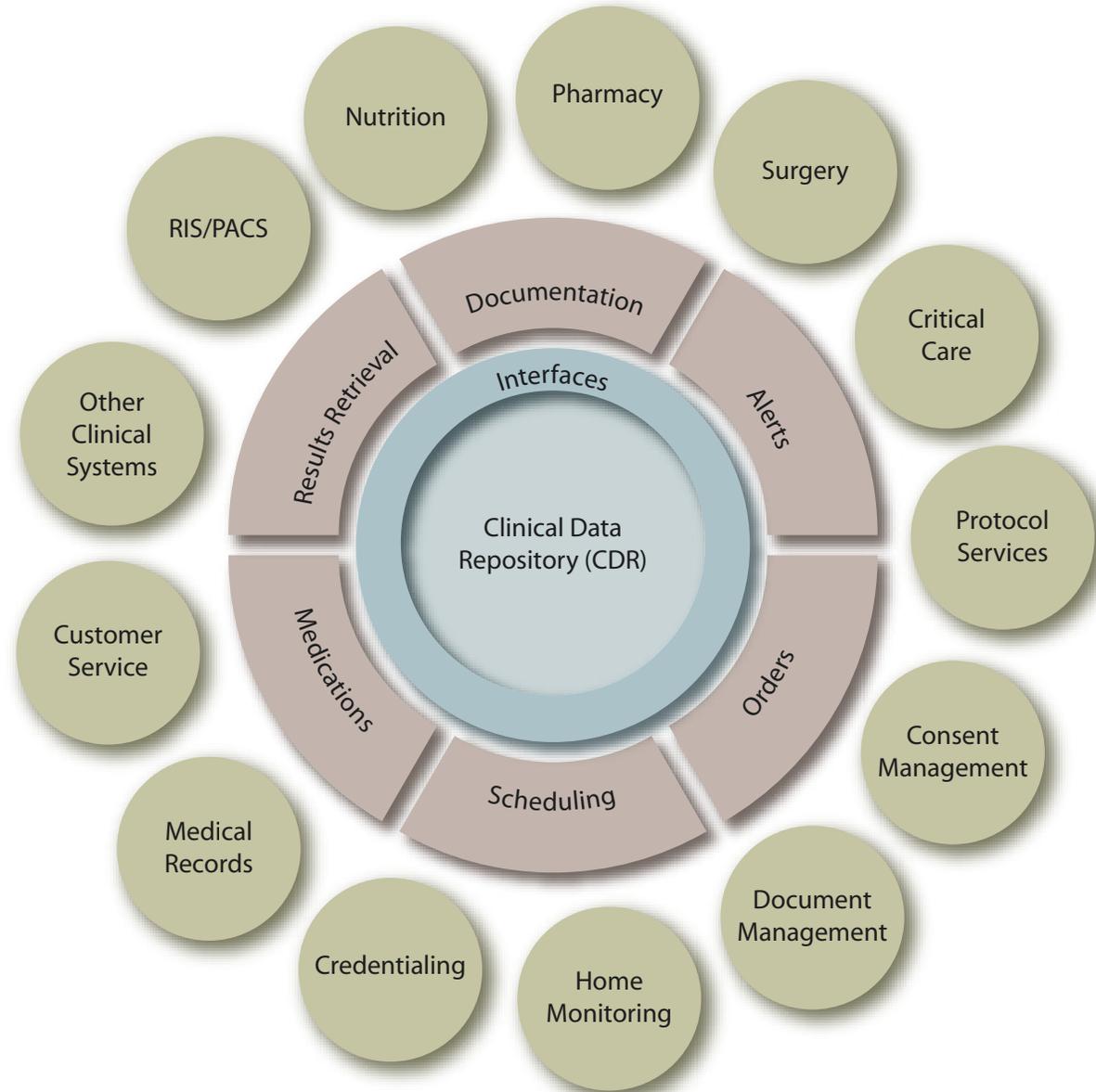
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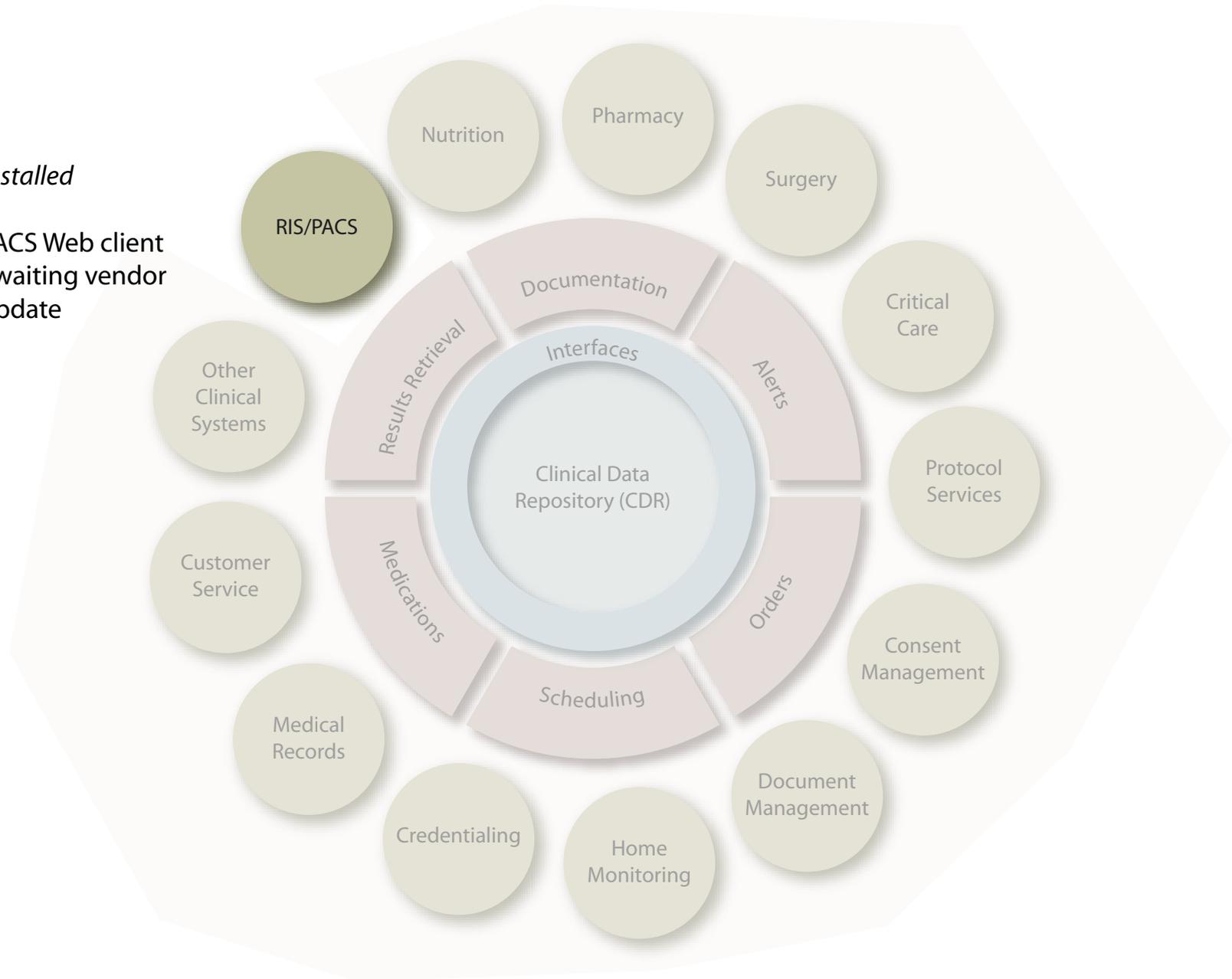
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*Installed*

PACS Web client  
awaiting vendor  
update





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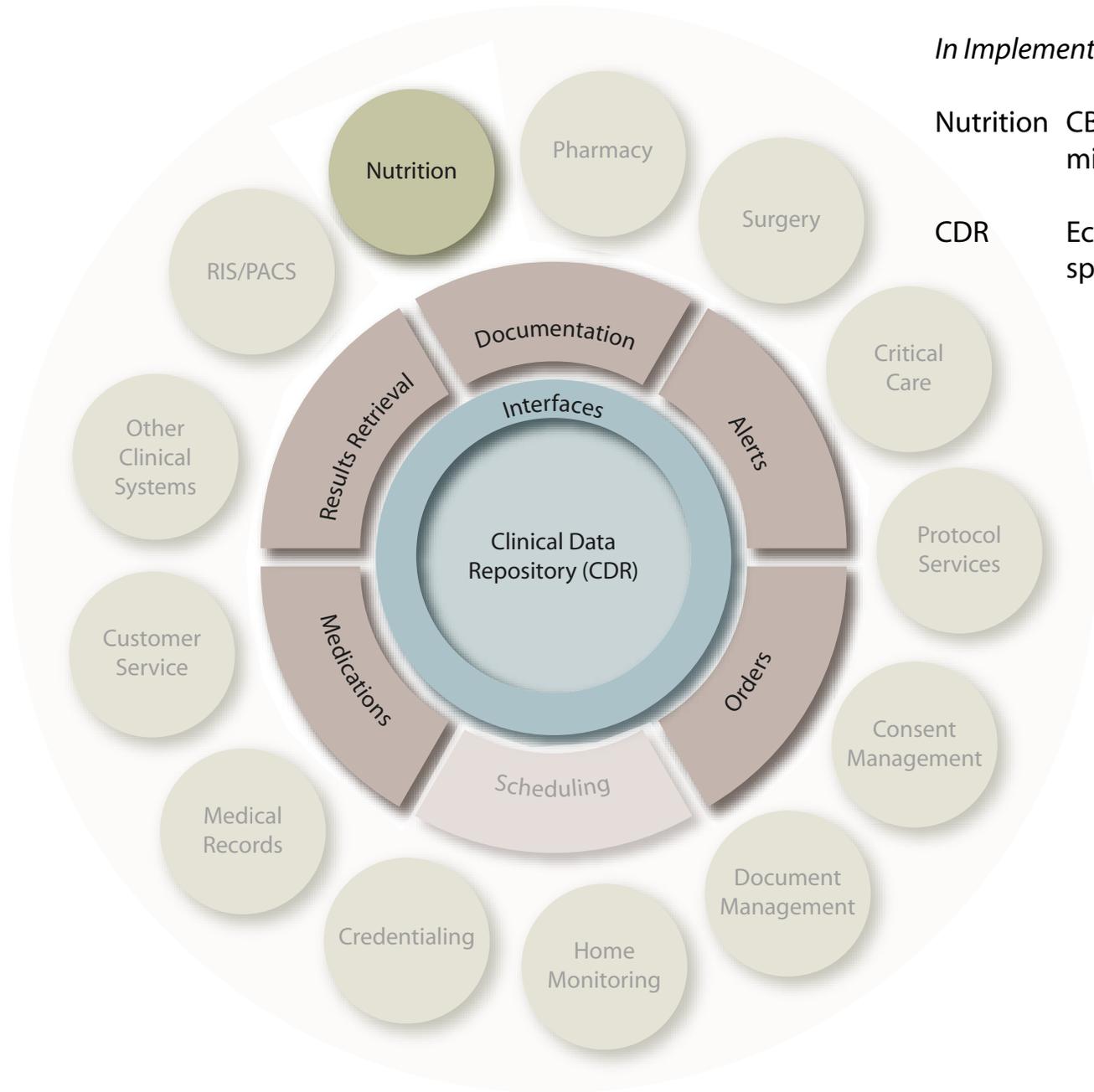
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*In Implementation*

Nutrition CBord  
mid-2003

CDR Eclipsys SCM  
spring 2004



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