Modeling the NPCR Restricted Access Data Set Release Process

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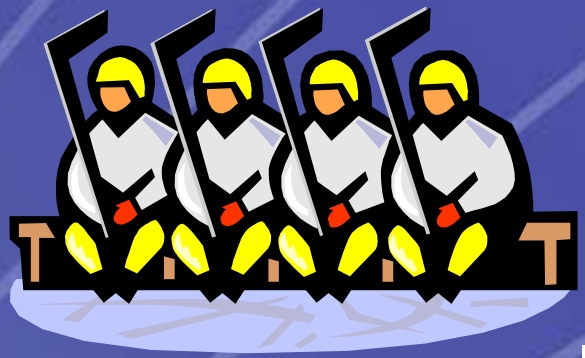
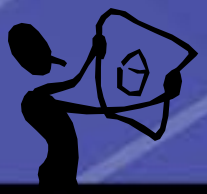


Background

- National Program of Cancer Registries (NPCR) registries report the data annually to CDC since 2001
- NPCR receives data from 45 states, DC and 3 US territories
- Following data submission, the registries receive a Data Evaluation Report
- High quality incidence data are used for United States Cancer Statistics and State Profiles and other data release products.
- In order for NPCR to provide researchers with cancer incidence data, a due process for data release has to be established.
- Existing cancer data release processes, could provide various elements for possible re-use with the NPCR process under design.

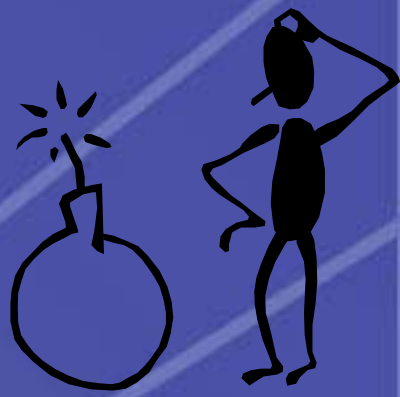


Purpose

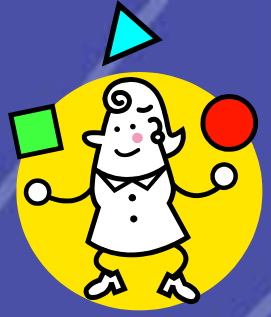
- The workgroup has been formed to develop a plan to share NPCR-CSS (or USCS) data with qualified researchers and to develop recommendations for the data release process.

Challenges

- Participants are:
  - Very limited in time to dedicate to project
  - Have diverse perspectives
  - Have limited experience in using formal methods to analyze and document business processes



Approach



- Incremental, consensus-based analysis and recommendations development process
- Facilitated modeling sessions – six sessions (two hours each) in the two and a half months period
- Preparatory “off-line” work of a Business Analyst (analysis of processes and development of modeling components) and “on-line” work of the Experts (review and critiques of these components)
- Business Modeling techniques
- Facilitation techniques
- UML – Unified Modeling Language

Why Business Modeling?

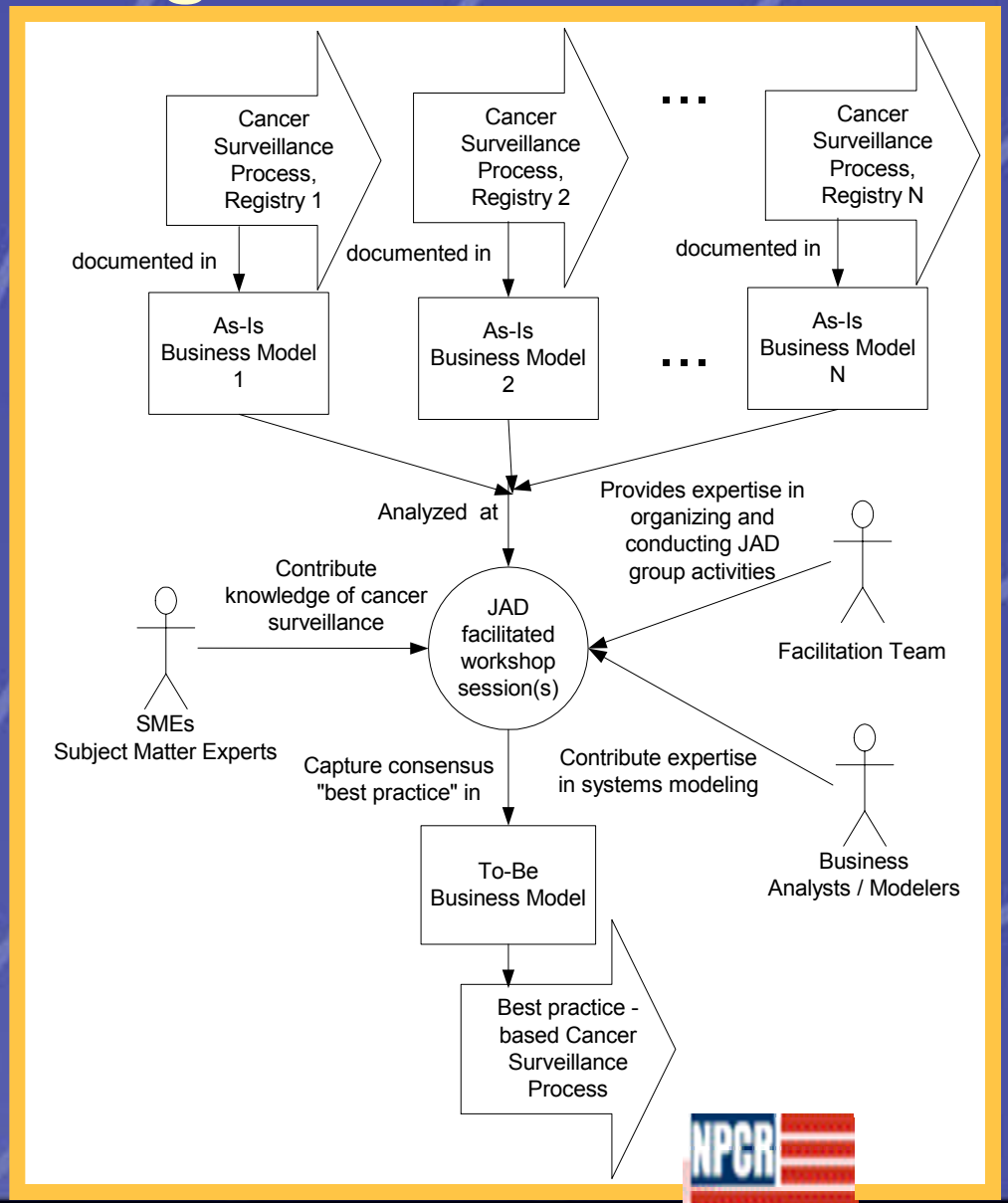
- Business modeling and facilitation techniques:
  - Helps us to communicate and to reach a consensus.
  - Helps us to document our business in a standard engineering “blueprint”.
  - Helps us to reduce a complexity of our business by reflecting it in different types of diagrams and other artifacts.
  - Provides requirements for IT systems development, makes sure that business needs will drive technology solutions, and not the other way around.

How to put a model together: facilitated session

Discussing

Brainstorming

Reaching consensus



Results

- Workgroup developed recommendations for the NPCR RADS release process in the form of a business model:
  - Step-by-step process descriptions
  - Business rules
  - Visual presentation in the form of a process diagram
  - Comparison table for different data release processes
- This model identifies major functional areas of cancer data release process, specific sequence of steps, and responsibilities of process participants.
- These recommendations provide a set of general technology-neutral functional requirements and NOT a description of specific solution/design or implementation.

Analysis of Existing Processes

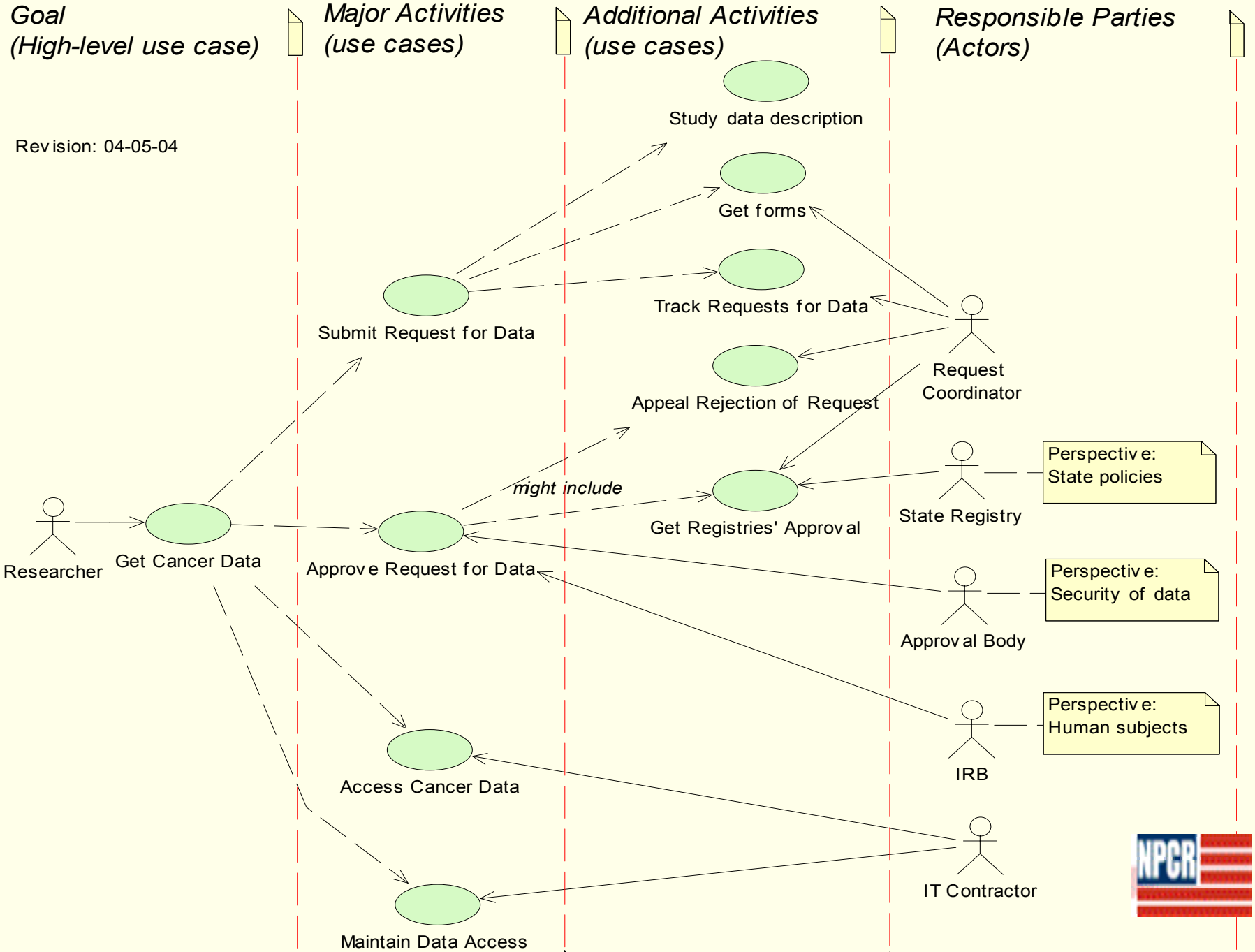
Major Functional Areas

- Submit request for data, including
  - Study data description
  - Get application forms
  - Track requests for data
- Approve request for data, including
  - Get registries' approval (consent)
  - Appeal rejection of request
- Access cancer data
- Maintain data access licenses

Process participants

- Researcher
- Request Coordinator
- State Registry
- Approval Body (in case of NPCR process - Data Release Workgroup)
- IRB
- IT Contractor

Use case diagram: Release of Restricted Access Cancer Data (typical functionality)



Comparison of Cancer Data Release Processes (fragment 1)

Functional Area	NPCR (under design)	NAACCR	SEER-Medicare	SEER
Submit request for data	Request is submitted to Request Coordinator. ~90% of Request Coordinator's responsibilities will be fulfilled by a Contractor, and ~10% - by CDC employee.	Request is submitted to NAACCR DEP Committee. Forms are available on-line.	Request is submitted to Admin (Contractor), who c/c to Coordinator. Forms are available on-line.	Request is submitted to SEER via the form at the web site. A personalized SEER Public-Use Data Agreement will be created for each request.
Track requests for data	Yes, it is necessary to keep a log of all actions pertinent to a request. Requests tracking IT system will have to be developed.	?	MS Access database, run by Contractor, accessible by Coordinator	In place; details unknown.
IRB Approval	External IRB approval or "exempt research" papers required for non-CDC researchers.	NAACCR IRB review is a part of the approval process	IRB approval is not required, but almost all requests have it anyway	Not required

Comparison of Cancer Data Release Processes (fragment 2)

Functional Area	NPCR (under design)	NAACCR	SEER-Medicare	SEER
Approve request for data	Data Release Workgroup	1) Data Evaluation and Publication Committee (CINA Deluxe sub-Committee?) 2) NAACCR IRB	1)Request is sent to a single registry selected in revolving order (as per telephone interview) 2) Representatives of NCI, SEER, and CMS review and approve (as per web site)	SEER; details unknown.
Appeal process	Through Request Coordinator	?	Not formally defined; need for appeal never aroused.	?
Get permissions from registries	Not required for many (44?) registries. For the rest of registries – Researcher can be tasked to obtain consents (?) Need to survey states about willingness to participate in RADS and give authority to Data Release Group. The other option is to get permission project by project (unacceptable, by Group's opinion)	Each registry gives consent for release of data on a project-by-project basis.	A single registry approves a request in behalf of all registries	Not required

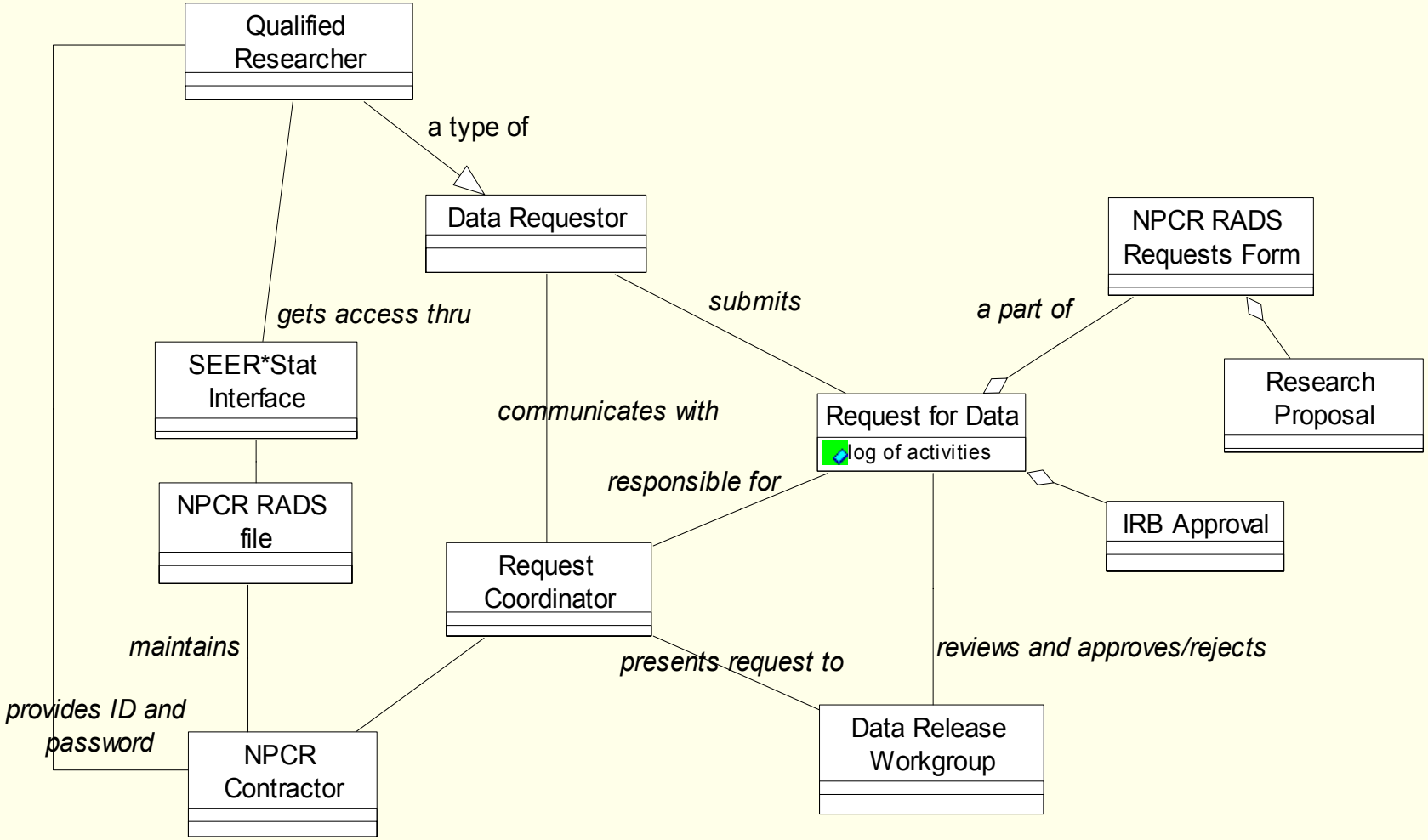
Comparison of Cancer Data Release Processes (fragment 3)

Functional Area	NPCR (under design)	NAACCR	SEER-Medicare	SEER
Customization of cancer data	No	Yes	Yes	No
Charging for data	No	No	Yes – SEER contractor has to be compensated for preparing custom data by outside researchers	No
Access cancer data	Electronic access to data thru SEER*Stat	Electronic access to data thru SEER*Stat	Data file is sent to Researcher	1. Use SEER*Stat to access the data through your Internet connection (SEER*Stat's client-server mode) 2. Have CDs containing the data and SEER*Stat software shipped to you. These include the binary and text versions of the data. 3. Download two compressed files containing the CD images. SEER*Stat, the binary data, and the text data are available for download.

Comparison of Cancer Data Release Processes (fragment 4)

Functional Area	NPCR (under design)	NAACCR	SEER-Medicare	SEER
Maintain data access licenses	Revoked after one (1) year. Request for extension (continuation form) can be filed after that.	Revoked after one (1) year. Request for extension can be filed after that.	Don't have a requirement to destroy the data after certain period of time (used to be 5 years)	?
Establish Data Research Center	No. Could be considered as a last resort.	No	No	No
Who can be served?	Stage 1. (Year of 2005) NCI - no SEER-Stat software in use at this point. Stage 2. Researchers from US cancer registries and national partners. Stage 3. Any researcher representing a USA institution Requests from outside of the USA will be dealt with if/as they come.	NAACCR Researcher (from the NAACCR registry)	Outside and inside (from a SEER Registry) Researchers. No requests for data from outside of USA were made.	Restrictions unknown.

NPCR RADS release process Domain diagram (draft)



Business rules

BP #	Theme / Area	Business Rule statement	High-level business motivation aimed for by the Best Practice	Remarks / Links
BR01	Available Data	No customization of NPCR RADS file is offered, only pre-build files are available.	Minimize efforts, increase security.	
BR02	Access to data	Data is not given away, only password-protected limited access to data thru a software like SEER*Stat.	Increase security.	
BR03	Access to data	Only Qualified Researchers can get access to NPCR RADS file.	Serve only valid requests for data, reduce amount of requests.	
BR04	Access to data	Qualified Researcher is defined as a Researcher who: a) Can provide a research proposal with approval of non-CDC Federally approved IRB board or "exempt research" papers (for external researchers) or from CDC IRB (for internal – CDC researchers). b) Represents NCI (during the first stage - 2005). Represents cancer registries or national partners (during the second stage). Represents a USA institution (during the third stage).	Serve only valid requests for data, reduce amount of requests.	
BR05	Access to data	Access to NPCR RADS data is granted for a limited period of time – one (1) year.	Increase security.	
BR06	Data use agreement	Researchers may not publish or present findings in which the number of cases in a cell, by registry, is less than five.	To eliminate the potential for re-identification of patients	Based on SEER-Medicare: http://healthservices.cancer.gov/seermedicare/obtain/use.html

Process description (excerpt) - 1

- **Process participants:**
  1. Researcher
  2. Request Coordinator
  3. Data Release Workgroup
  4. NPCR Contractor
- **Preconditions:**

What must be true in order for process to be possible to start.

1. RADS is created and ready for release.
2. RADS data description is available to Researchers for review.
3. Forms necessary for requesting the data are developed and available to Researchers.
4. Permissions are obtained for re-release of State registries data in NPCR RADS.

Process description (excerpt) - 2

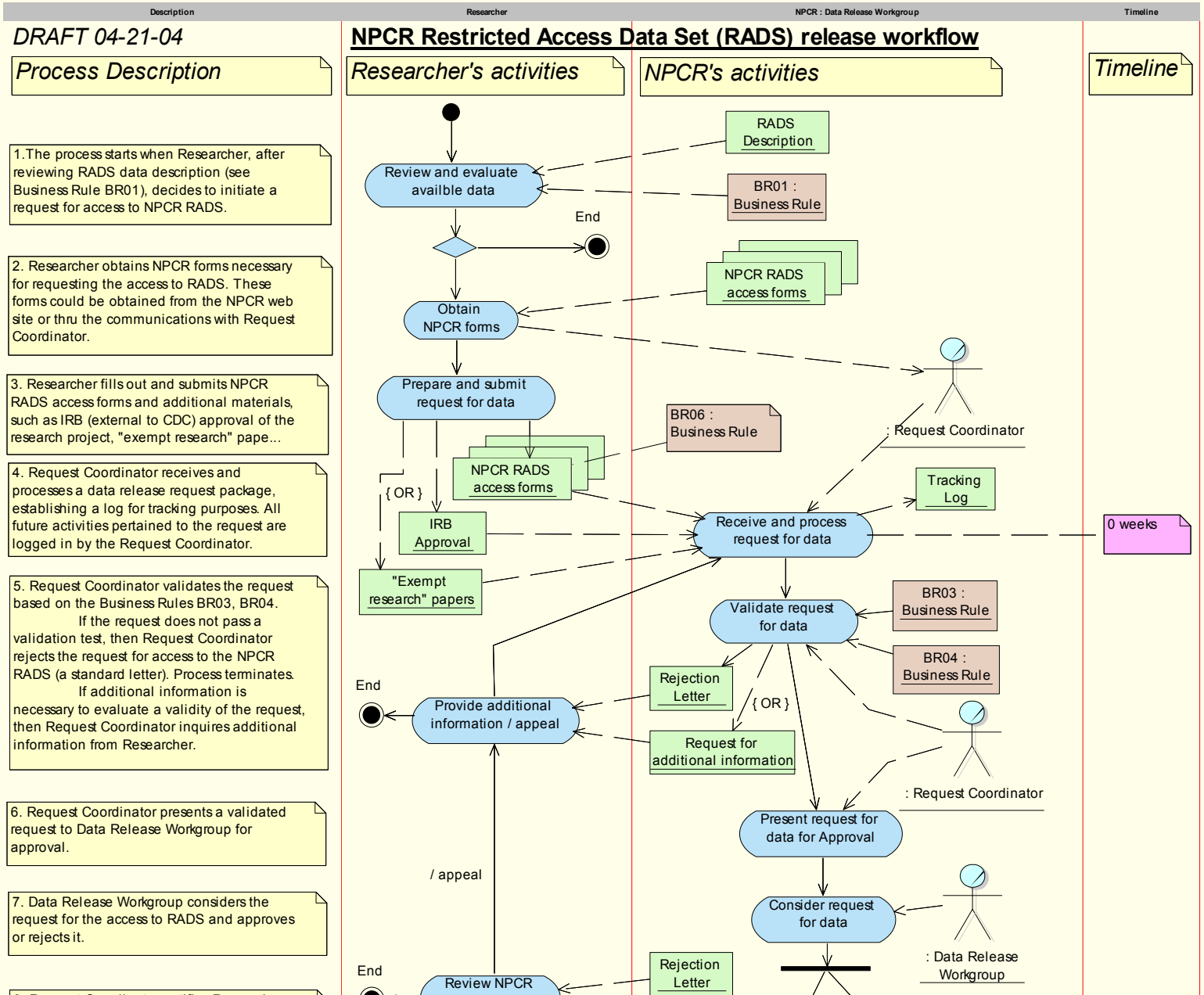
1. The process starts when Researcher, after reviewing RADS data description (see Business Rule BR01), decides to initiate a request for access to NPCR RADS.

2. Researcher obtains NPCR forms necessary for requesting the access to RADS.

These forms can be obtained from the NPCR web site or thru the communications with Request Coordinator.

3. Researcher fills out and submits NPCR RADS access forms (BR06) and additional materials, such as IRB (external to CDC) approval of the research project, “exempt research” papers, etc.

Process diagram



Process diagram (continues)

5. Request Coordinator validates the request based on the Business Rules BR03, BR04.
If the request does not pass a validation test, then Request Coordinator rejects the request for access to the NPCR RADS (a standard letter). Process terminates.
If additional information is necessary to evaluate a validity of the request, then Request Coordinator inquires additional information from Researcher.

6. Request Coordinator presents a validated request to Data Release Workgroup for approval.

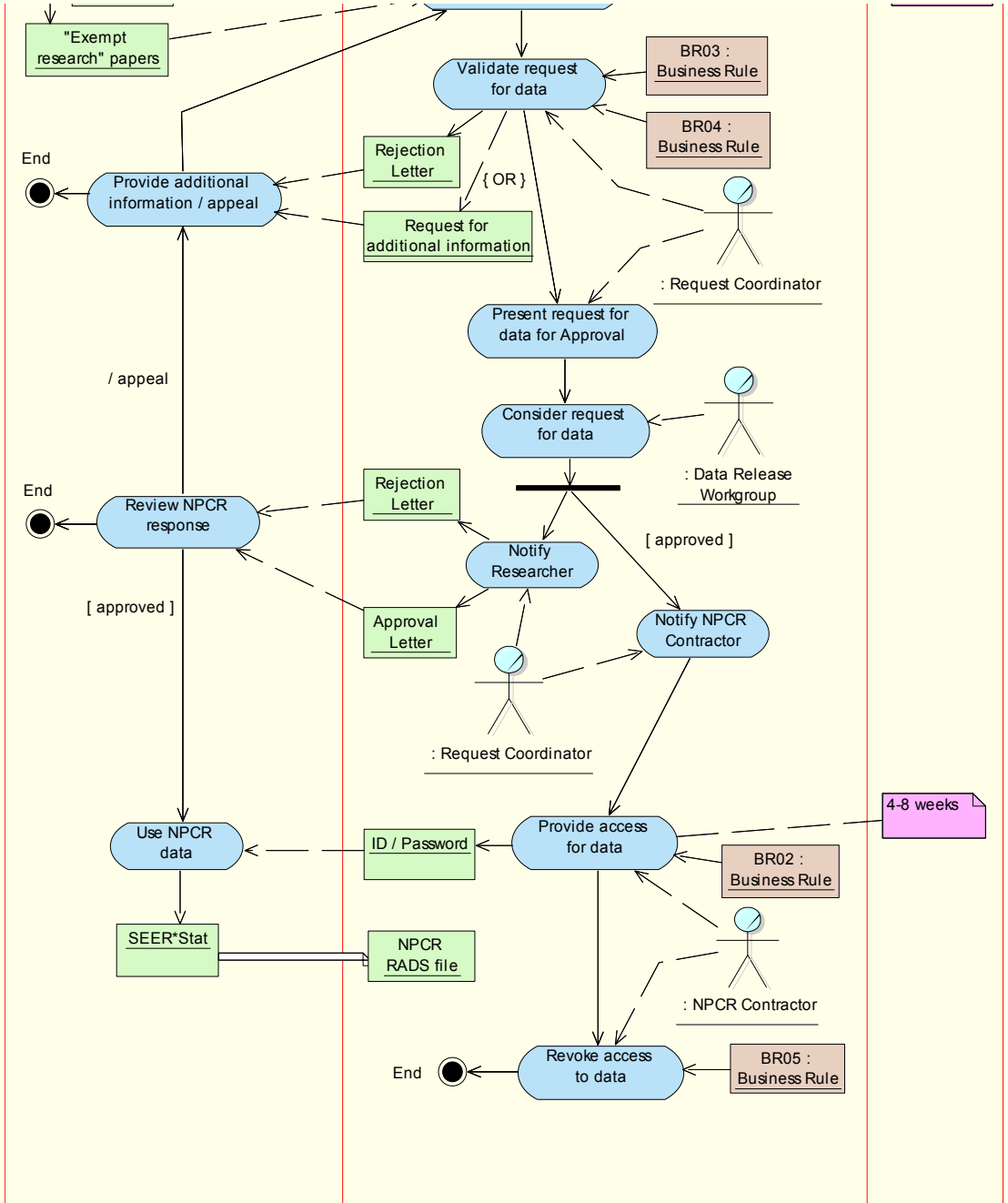
7. Data Release Workgroup considers the request for the access to RADS and approves or rejects it.

8. Request Coordinator notifies Researcher about decision regarding the request for the access to NPCR RADS (standard letter).
If request is approved, then the process continues.
If request is rejected, then < Researcher can appeal ?>

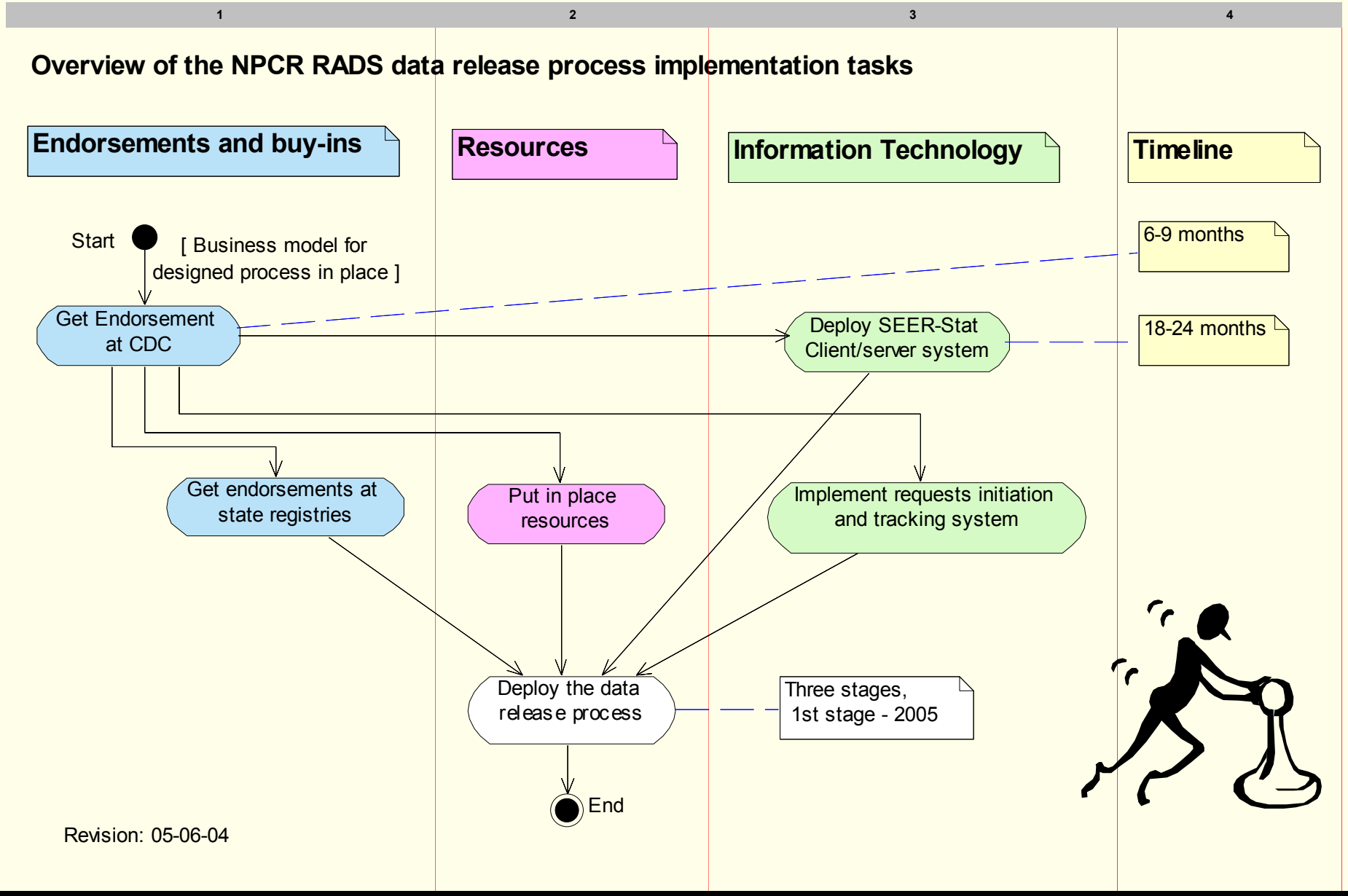
9. Request Coordinator directs NPCR Contractor to provide Researcher with access to NPCR RADS.

10. NPCR Contractor provides Researcher with user ID and password to access NPCR RADS via standard SEER*Stat software interface (see Business Rule BR02).

11. When the access period is expired, NPCR Contractor revokes the Researcher's access to NPCR RADS (see Business Rule BR05). The process ends.



Implementation tasks



Conclusions

- A modern approach based on business engineering techniques was used to develop recommendations for the NPCR RADS release process.
- Developed business model facilitates analysis and documentation of the data release process and provides a basis for information technology systems requirements.
- Presented materials are work in progress; at this time not all internal details of SEER and NAACCR processes are known and available for analysis.

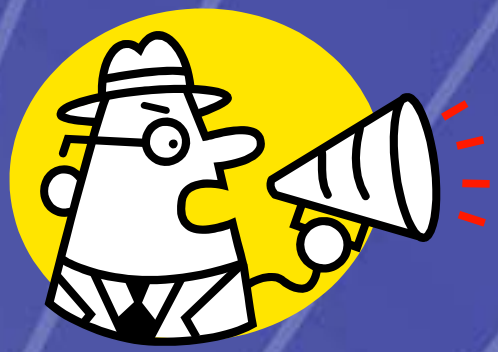
Take Home Messages

1) Designed RADS release process expressed in standard engineering formats that support better communication, understanding, and consensus building.

2) Business modeling and facilitation techniques:

- Provided an adequate support to participants.
- Helped to reach a consensus among participants
- Helped to produce “technology neutral” solutions and recommendations.

Questions?



The End

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