



Collecting 48,000 CT Exams for the Lung Screening Study (LSS) of the National Lung Screening Trial (NLST)

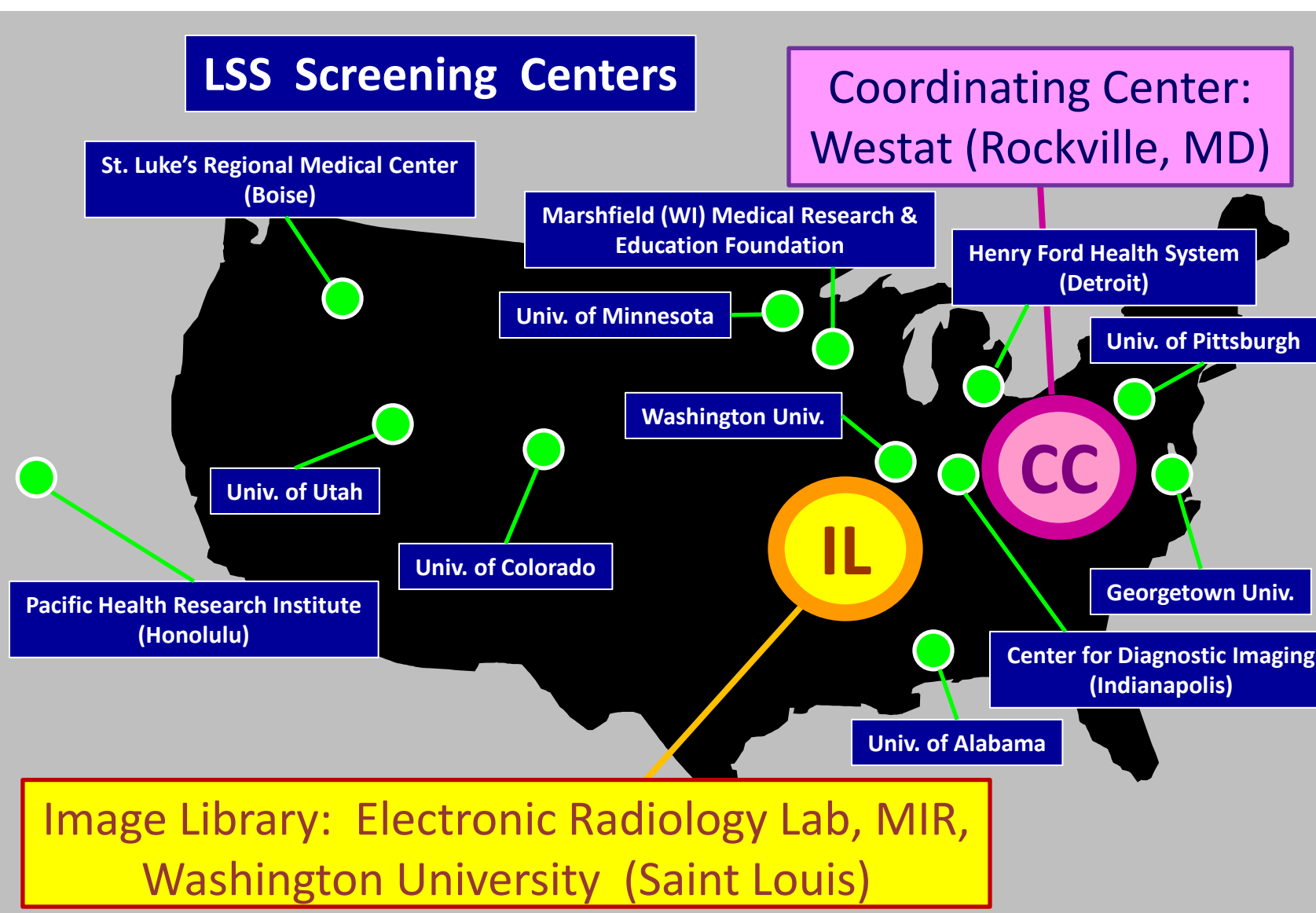
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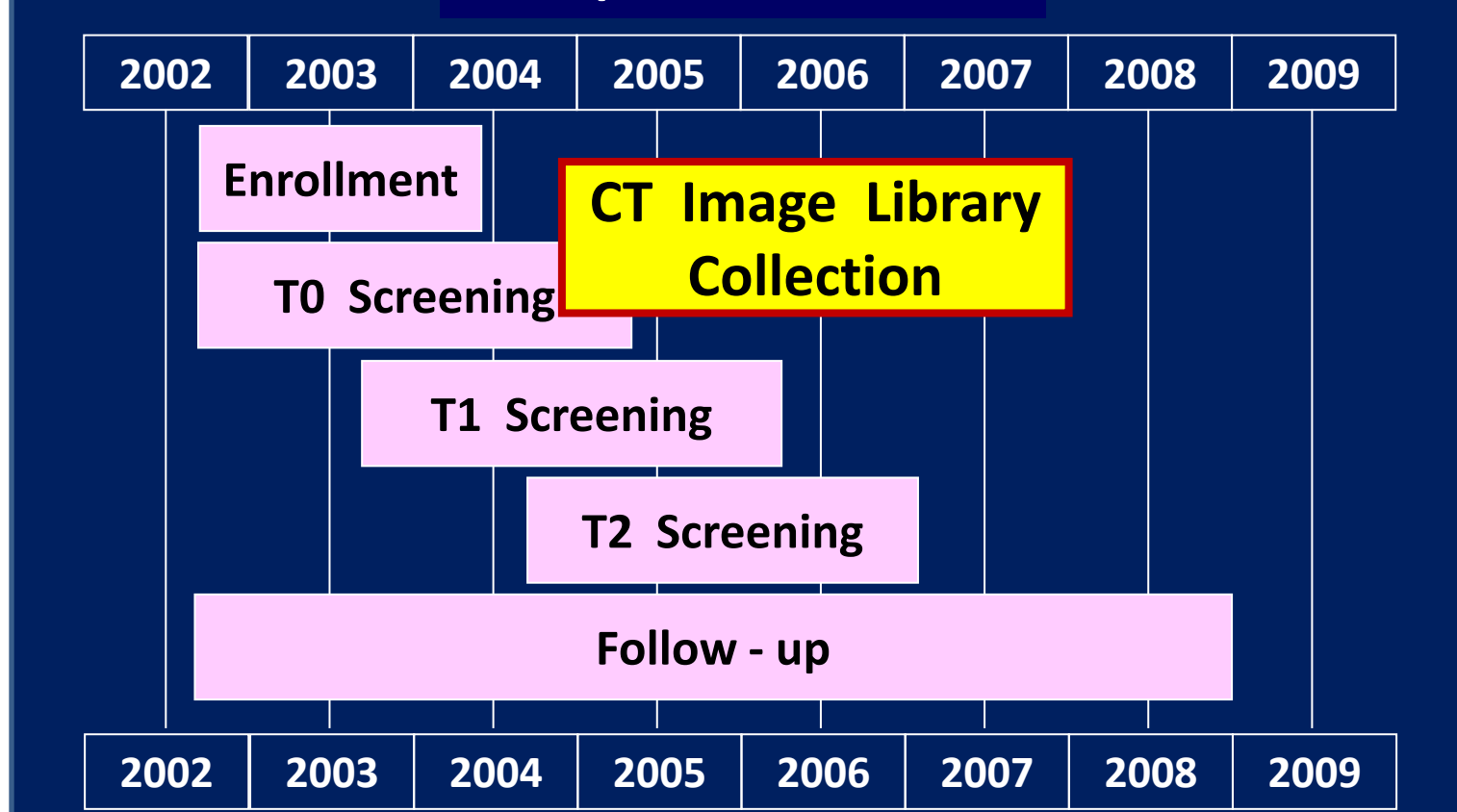


BACKGROUND

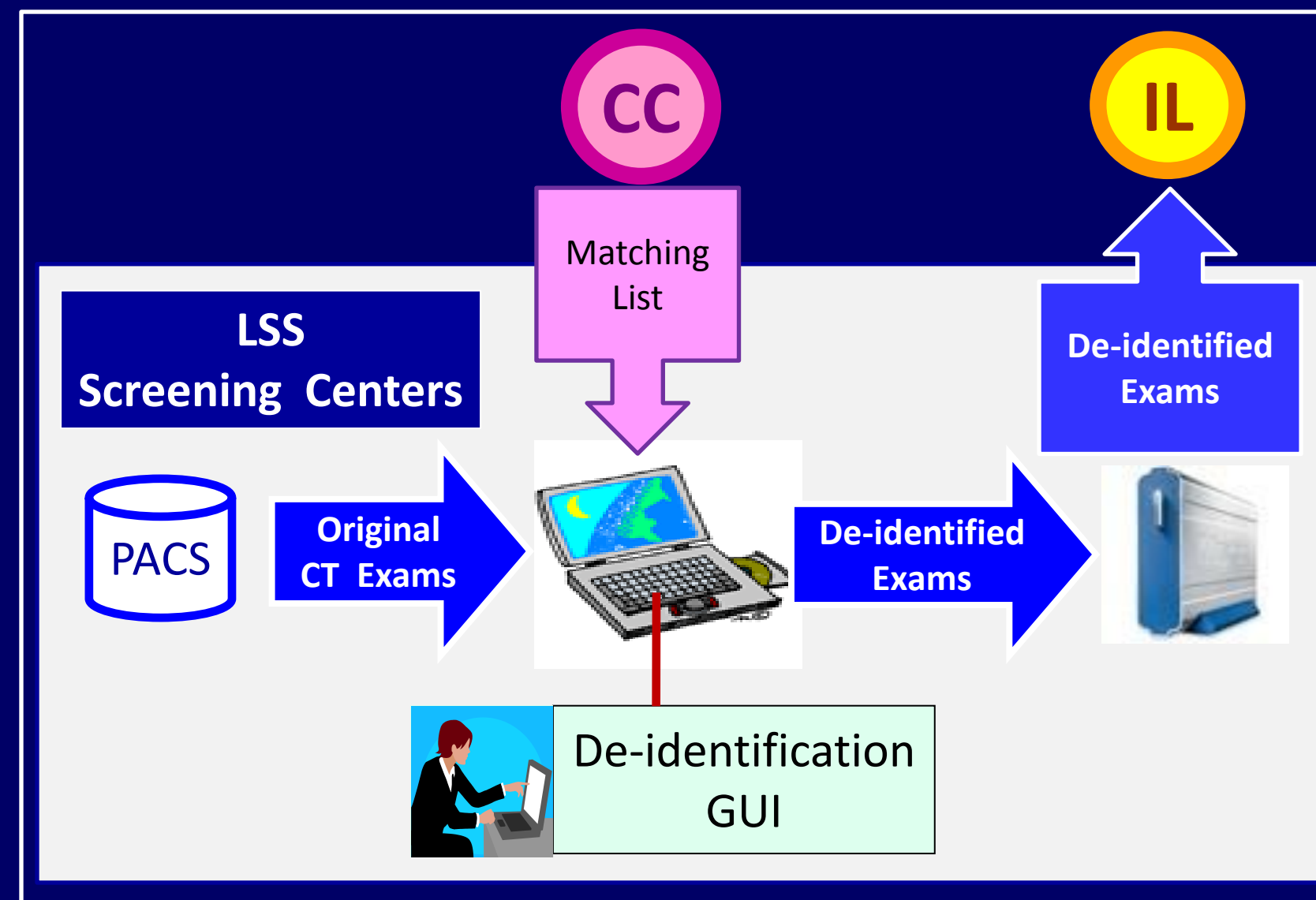
From 2002-2004, the Lung Screening Study (LSS) of the National Lung Screening Trial (NLST) enrolled 34,614 participants, aged 55-74 years, at risk for lung cancer due to heavy cigarette smoking. Participants were randomized to chest X-ray (CXR) or computed tomography (CT) arms through 12 screening centers and received up to 3 imaging screens at annual intervals. Available CT exams (48,547) were de-identified of protected health information and delivered to a CT Image Library (CTIL) at Washington University where stringent quality assurance measures (automated checks of DICOM headers and visual inspection of images) were applied before images were archived. Associated baseline medical histories, medical updates at screening, and radiologist interpretations of images are maintained at Westat, an independent research firm contracted to manage the LSS. The CT exams are now available, on a restricted basis, to clinical-research and imaging-science investigators. Summarized here are the CT data available from the CTIL, as well as guidelines by which investigators may gain access to the images.



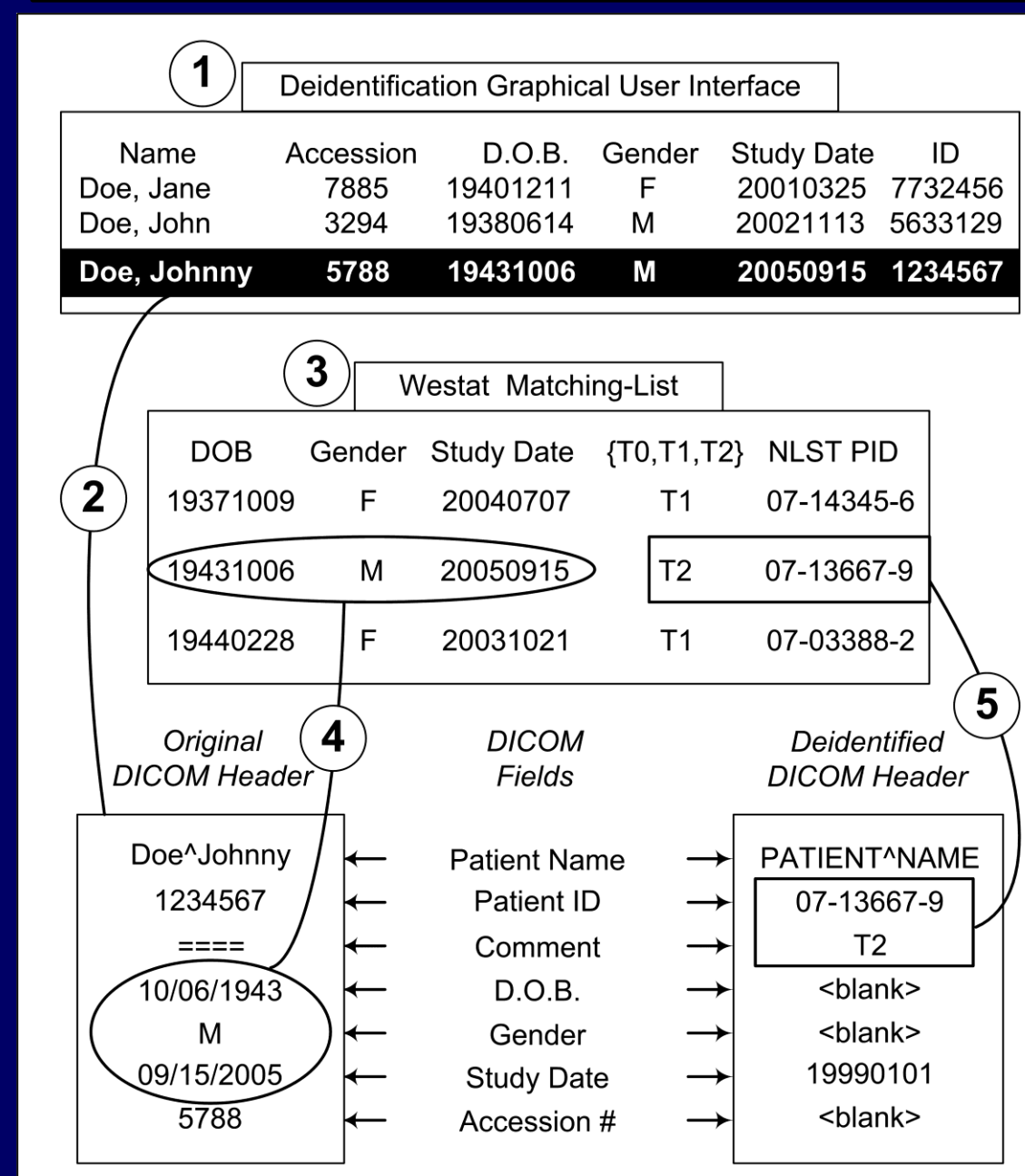
NLST / LSS TIME LINE



DE-IDENTIFICATION PROCESS



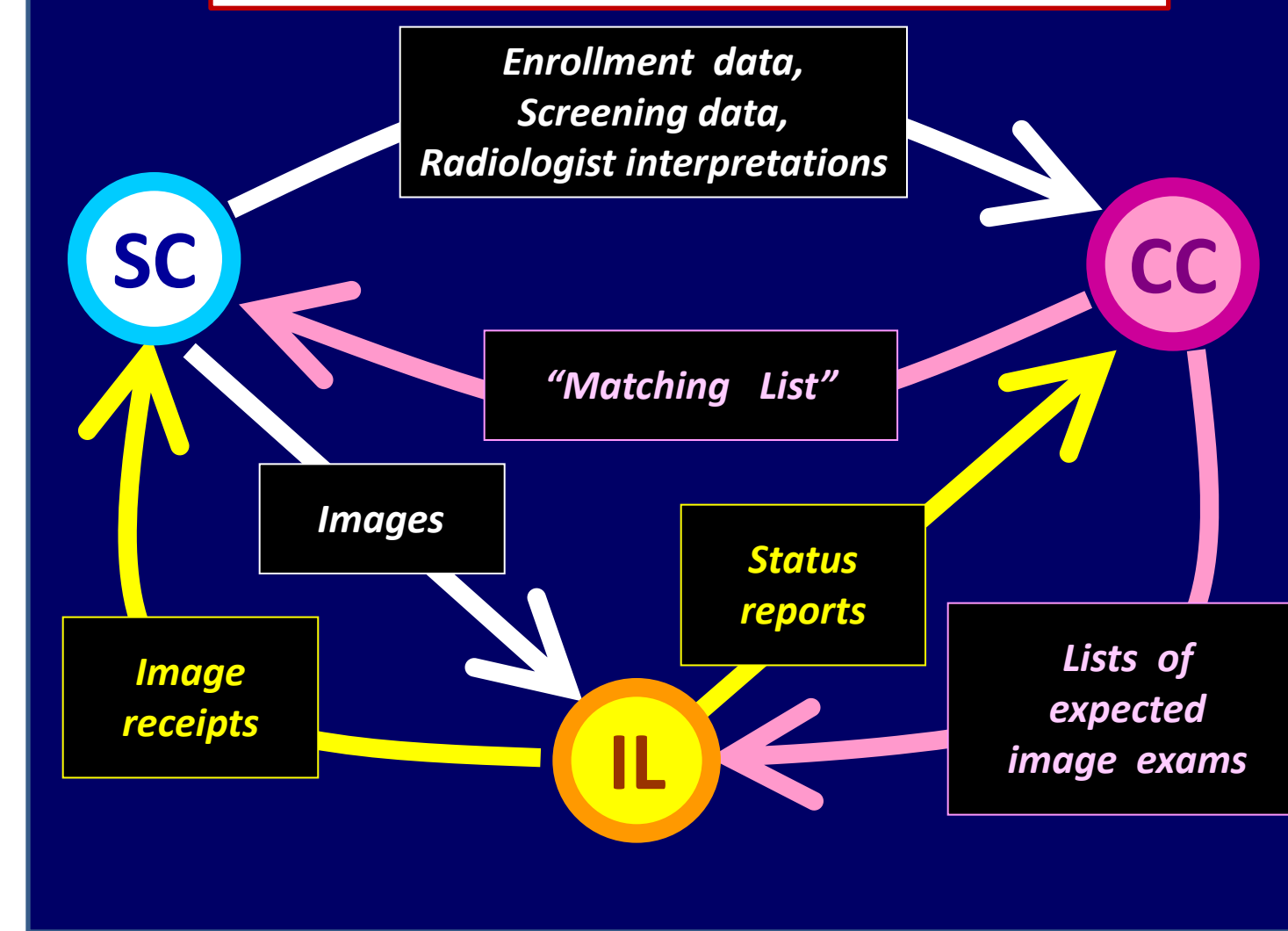
DE-IDENTIFICATION DETAILS



LEGEND for DE-IDENTIFICATION DETAILS

- User selects an exam in the graphical user interface (GUI).
- Upon selection, the GUI links to the exam's DICOM header data and searches the (3) Matching List until it finds a line where (4) DOB, Gender, and Exam Date match those of the DICOM header. (5) If a match is made, a new de-identified DICOM header is created (lower right). In the new header, an NLST PID replaces the local Patient ID, and the screening year {T0,T1,T2} is recorded in a Comment field. The patient's name becomes a generic PATIENT^NAME and Study Date a generic "19990101"; DOB and Gender are blanked as are other DICOM fields likely to contain protected health information.

COORDINATION AMONG SCs, CC, IL



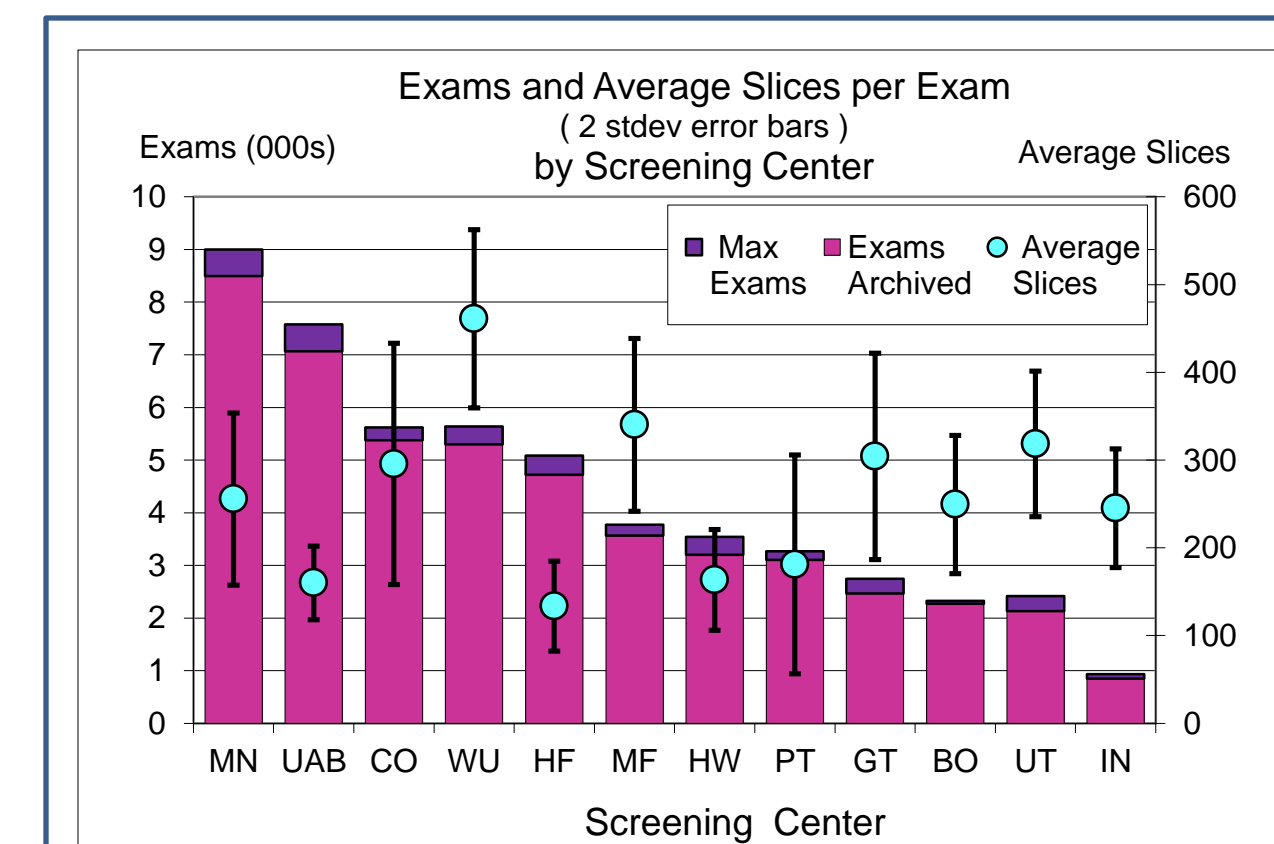
Quality Assurance Checks

Automated Inspection of DICOM Headers

- NLST - PID Valid?
- Image Counts Reasonable?
- Protocol - valid Reconstruction Kernel?
- Proper Image - slice Spacing?
- Proper Image - slice Thickness?
- DICOM Headers Free of PHI?

Visual Inspection of All Images

- Images Free of PHI?
- Images of Good Quality?
- Lung Coverage Complete?
- Missing Images?
- Extra Images?



The number of slices/exam varied, primarily due to the number of image series reconstructed and minor differences in slice thickness.

CT IMAGE LIBRARY -- BY THE NUMBERS

- # CT Participants - 17,309
- Max # CT Exams - 51,927
- # CT Exams Performed - 48,723
- # CT Exams Archived - 48,547 (99.7%)
- # CT Exams Unavailable - 176 (0.3%) (lost, corrupt, compressed)
- CTIL Size - 12,466,488 images (6.2 TB)

ACCESSING CT IMAGE LIBRARY EXAMS

CTIL images are not yet publicly available, nor are blinded participant medical data and screening results. These restrictions remain in effect until after the NLST follow-up period completes in 2009. However, images may still be requested by investigators on a limited basis. The provisioning of CTIL images is 2-step process:

- An investigator submits a proposal to Westat, specifying the kinds and numbers of images, as well as research summary-plan. Westat has the ability to match medical history, medical follow-up data, and screening results with CTIL exams. If the images are available, the research plan must be approved by NCI; if unavailable, Westat asks the investigator to recast the request. Images available and approvals in hand, Westat notifies the CTIL which CT exams to prepare for the investigator.
- CTIL personnel then pull the requested exams from the library and deliver them to the investigator. The exams may be transmitted over a secure Internet connection or shipped on media provided by the investigator.

KW Clark, DS Gierada, G. Marquez, SM Moore, DR Maffitt, JD Moulton, MA Wolfsberger, P Koppel, SR Phillips, FW Prior. "Collecting 48,000 CT Exams for the Lung Screening Study of the National Lung Screening Trial", J. Digital Imaging (accepted for publication, Aug. 2008), DOI: 10.1007/s10278-008-9145-9.

SUPPORT

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