Incidental Pulmonary Nodule Programs versus CT Lung Screening and How They Compare

Debra S Dyer MD FACR
Thoracic Radiologist
National Jewish Health
Denver

Disclosures

- Consultant and Speaker, Lung Ambition Alliance
- Member, Clinical Advisory Board, Imidex
- Member, Scientific Advisory Board, GO2 Foundation for Lung Cancer

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Objectives

- Compare IPN and LCS strategies
- Review incidence and significance of IPNs
- Outline challenges and opportunities in monitoring IPNs
- Describe Nodule Tracking System and Lung Nodule Registry at National Jewish Health
- Discuss how an Incidental Pulmonary Nodule Program and LCS can improve the early detection of lung cancer

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IPN and LCS Programs – How do they differ?

IPNs	LCS
Lower pre-test probability of lung cancer	Higher pretest probability of lung cancer
Opportunistic screening	Intentional screening
Routine Chest CTs and CTAs	LDCT of the Chest
Very high volume performed	Modest volume performed
Higher yield due to large volume	Lower yield
Patients from numerous referring providers and ER	Patients selected and appropriately referred
Usually no dedicated staff or resources	Usually dedicated navigator
No pre-imaging commitment to diagnosis and treatment	Patient has participated in Shared Decision Making and committed to diagnosis and treatment
Fleischner Guidelines	LungRADS or IELCAP
Follow-up more challenging, less control	Follow-up easier, more control, expectation patient will return for next annual screen

IPN and LCS – How are they similar?

- Both identify suspicious lung nodules
- Both should be reviewed at Multidisciplinary Conference/Nodule Clinic
- Both can lead to the early detection of lung cancer
- Diagnostic and treatment options are similar

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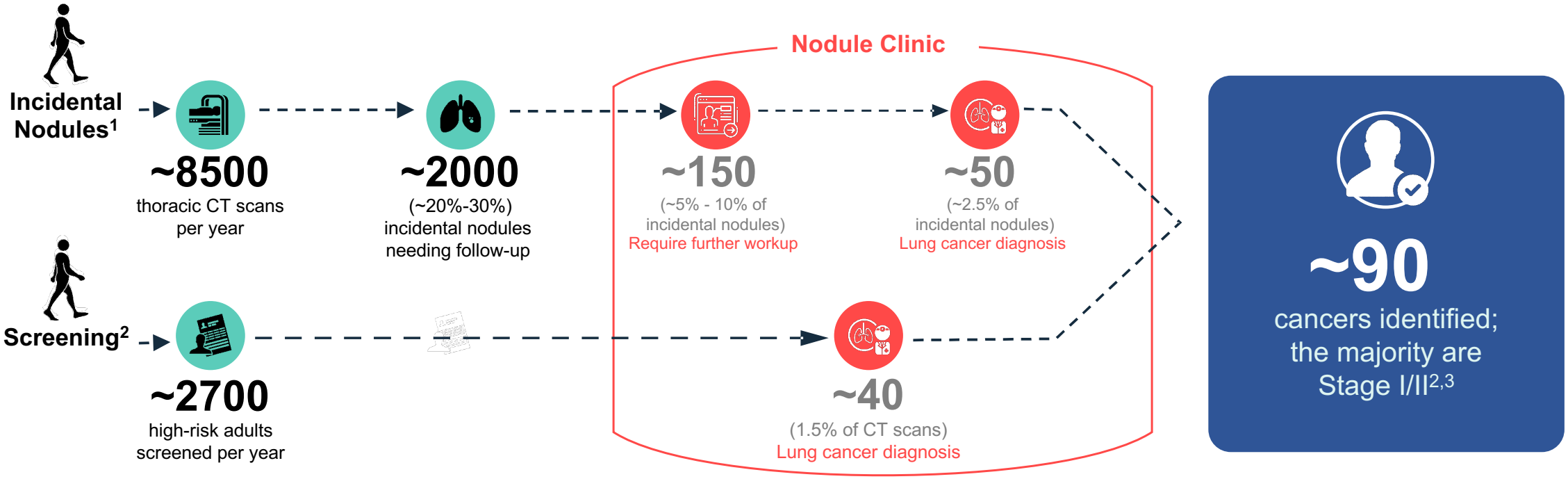
IPN and LCS Programs are Complementary

Synergistic Pathways: Hypothetical Scenario[1,2]



ILNP and LDCT screening work together to increase the rate of early-stage lung cancer diagnoses

- CT, computed tomography; ILNP, Incidental Lung Nodule Program; LDCT, low-dose computed tomography.
- 1. Unpublished data shared with permission from Elizabeth Kern. Incidental Lung Nodules: Tracking and Managing for Early Lung Cancer Diagnosis. National Jewish Health, Denver, CO. 2. National Lung Cancer Roundtable. McKee A. CT Lung Screening Implementation Challenges: State Based Initiatives. December 2018. http://nlcrt.org/wp-content/uploads/Andrea-McKee.pdf. Accessed February 2, 2020. 3. Ho H, et al. *J Thorac Cardiovasc Surg.* 2020;S0022-5223(20)32573-3.

National Jewish Health Incidental Pulmonary Nodule Program vs LDCT Screening

Incidental Nodule Program

Out of **8500 clinical chest CTs**

↓

2100 (25%) with **incidental nodules** needing follow-up

↓

146 abnormalities requiring further workup (PET, biopsy)

↓

50 lung cancer cases diagnosed

LDCT Screening

Out of **569 lung LDCTs**

↓

110 (20%) with nodules needing follow-up

↓

66 abnormalities requiring further workup (PET, biopsy)

↓

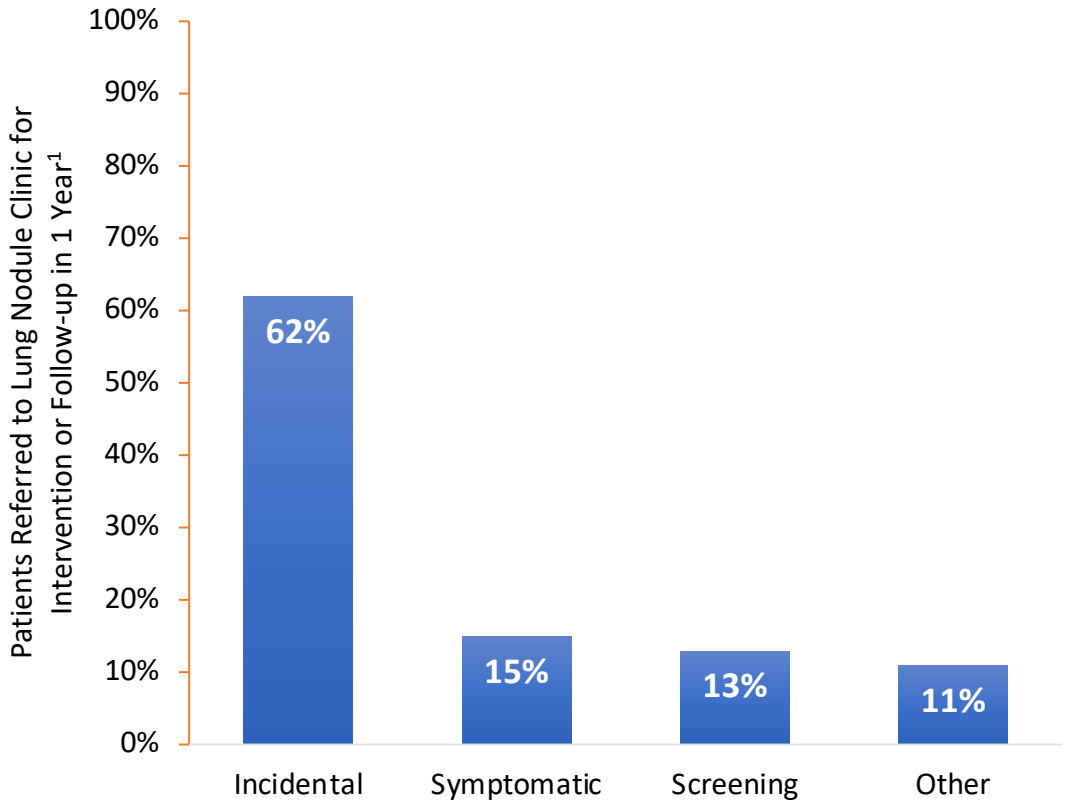
9 lung cancer cases diagnosed

At National Jewish Health, follow-up **of incidentally detected** lung nodules resulted in approximately 50 lung cancer diagnoses, with 9 diagnoses were made with LDCT screening

- CT, computed tomography; LDCT, low-dose computed tomography; PET, positron emission tomography; US, United States.
- Unpublished data shared with permission from Elizabeth Kern. Incidental Lung Nodules: Tracking and Managing for Early Lung Cancer Diagnosis. National Jewish Health, Denver, CO.

The Majority of Lung Nodules Are Incidentally Detected[1]

- In one study of 665 lung nodules[1,a]
  - 62% of lung nodules were incidentally detected on thoracic CT imaging for trauma, cardiac symptoms, or abdominal symptoms[1]
  - 15% were found In patients with symptoms attributed to lung disease[1]
  - 13% were identified in patients who qualified for annual LDCT screening[1,2,b]



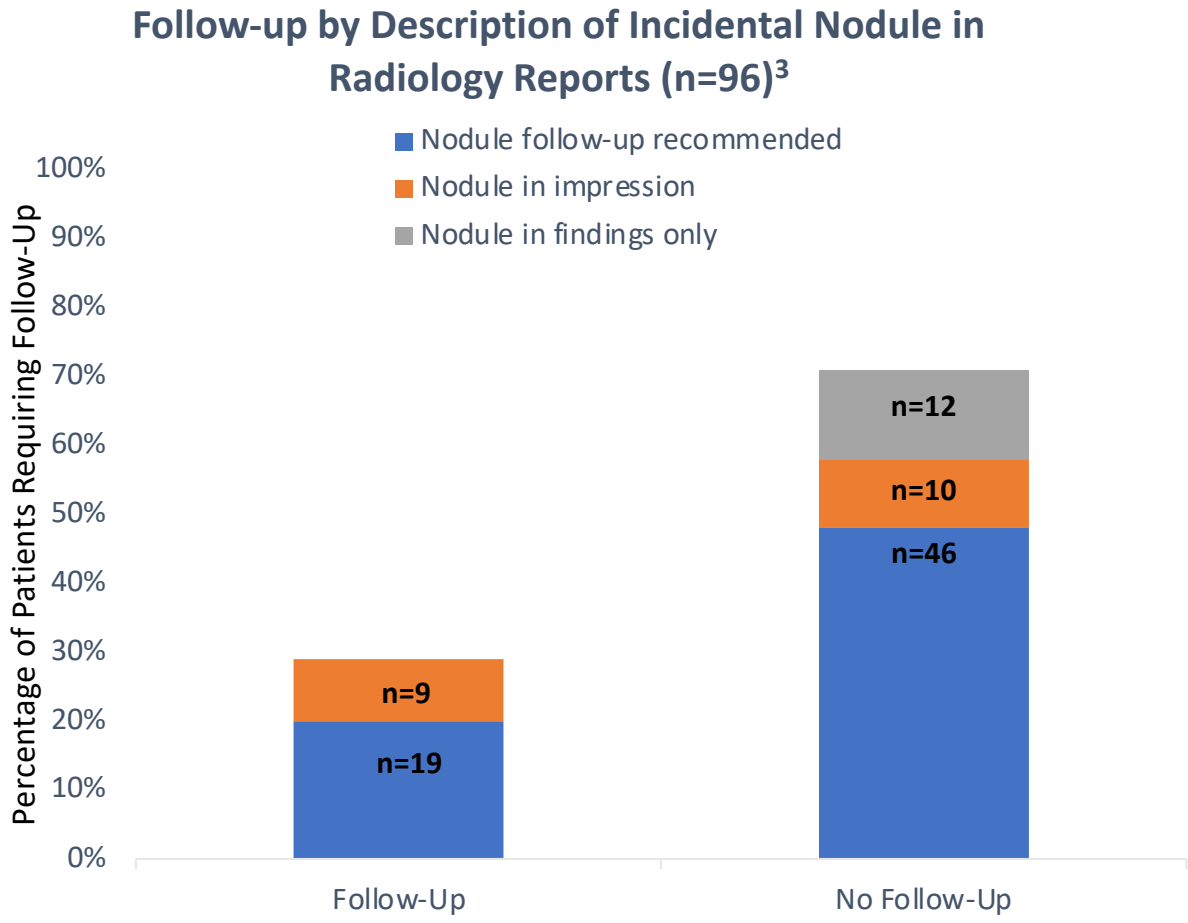
- [a]Retrospective analysis from a single-center, comprehensive lung nodule program at a community practice in Tennessee. [b]Adults aged 55-80 years who have a 30-pack year smoking history and currently smoke or have quit within the past 15 years. [c]Retropsective, observational study of chest CT imaging in KPSC, an integrated health care system, between 2006 and 2012.
- CT, computed tomography; LDCT, low-dose computed tomography.
- 1. LeMense GP, et al. *BMC Pulm Med*. 2020;20(1):115. 2. Moyer VA. U.S Preventative Services Task Force. *Ann Intern Med*. 2014;160(5):330-338. 3. Gould MK, et al. *Am J Respir Crit Care Med*. 2015;192(10):1208-1214.

Incidental Pulmonary Nodules Are Rarely Followed Up Despite the Potential Benefits for Early Identification of Lung Cancers

Approximately **2 out of 3 patients** with incidentally detected pulmonary nodules **receive no clinical follow-up**[1-3]

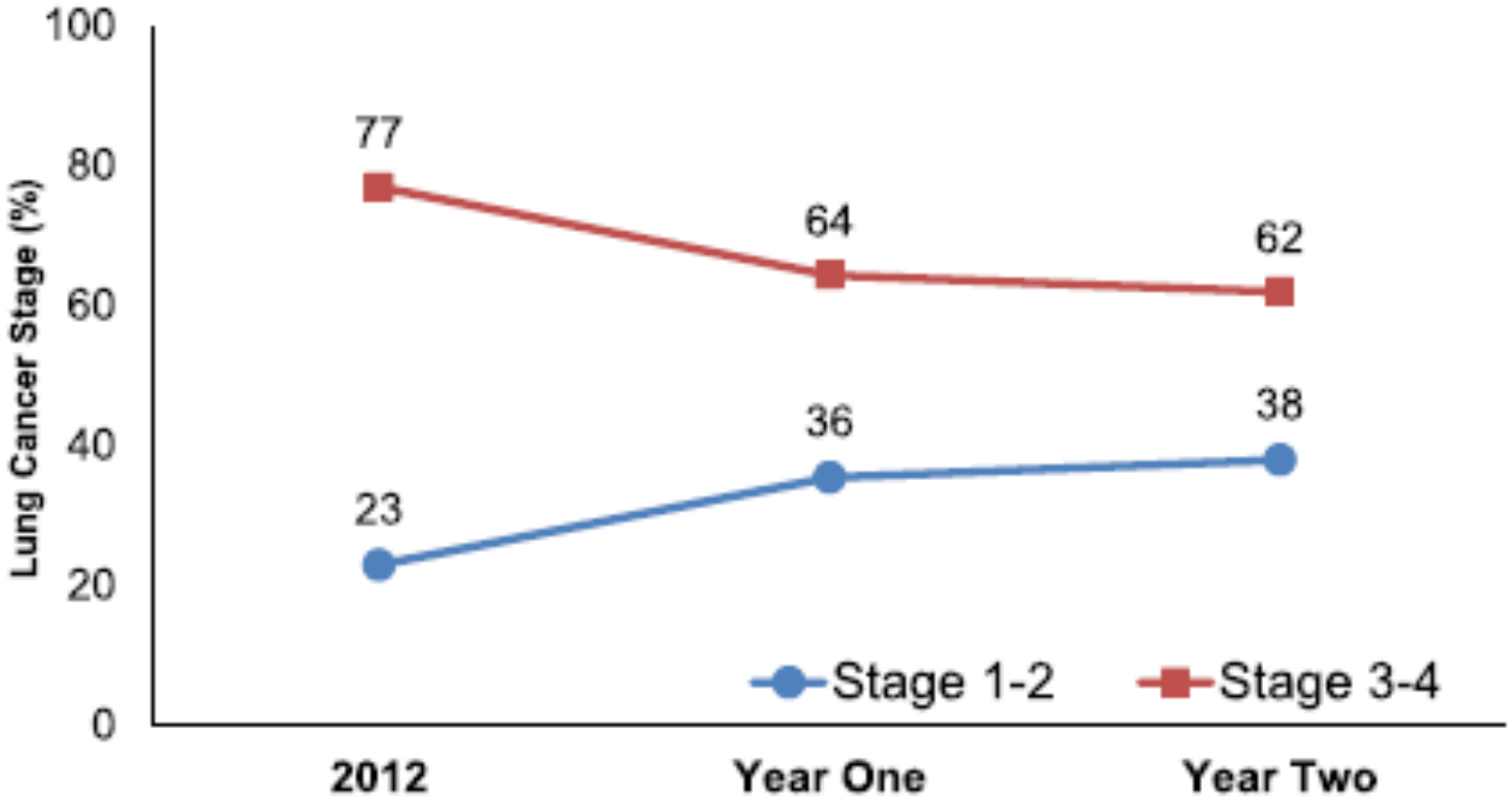
0% follow-up has been observed when incidental nodules are **mentioned only in the findings section** of the radiology report[3]

In 1 large study, the **mean time** from initial diagnosis of a pulmonary nodule **to first workup was 8 months**[2]



- 1. McDonald JS, et al. *Acad Radiol*. 2017;24(3):337-344. 2. Pyenson BS, et al. *J Health Econ Outcomes Res*. 2019;6(3):118-129. 3. Blagev DP, et al. *J Am Coll Radiol*. 2014;11(4):378-383.

Stage Shift with Comprehensive IPN Program



LeMense GP, et al. *BMC Pulm Med*. 2020;20(1):115.

Incidental Nodule Follow-up

- Studies show that adequate lung nodule follow-up ranges from 29% to 39%
- There is considerable variation among radiologists in how they report and manage incidental nodules
- Follow-up is less likely to happen:
  - When incidental nodules are mentioned only in the findings section of the radiology report and not in the Impression
  - When there is no convenient infrastructure embedded in dictation systems for radiologists to indicate follow-up recommendations
- Without clear concise guidance from the radiologist, clinicians are relying more and more on Natural Language Processing software to identify suspicious nodules
- Radiologists can adopt a standardized approach to nodule reporting & tracking and provide a valuable front-end to an Incidental Nodule Program

Pyenson BS, et al. *J Health Econ Outcomes Res*. 2019;6(3):118-129.; Blagev DP, et al.. *J Am Coll Radiol*. 2014;11(4):378-383.;

McDonald JS, et al. *Acad Radiol*. 2017;24(3):337- 344.

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IPN Management Program at National Jewish Health

- Development of Tracker phrase system based on Fleischner Society guidelines
- Radiologists provide Tracker phrases at the end of their reports which initiates the tracking process
- Tracker phrases are imported into NJH Lung Nodule Registry
- The Registry monitors patient compliance with needed follow-up
- Patients with suspicious nodules are reviewed at weekly Suspicious Nodule Conference

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Menu of Tracker Phrases updated to 2017 Fleischner

For CT Follow-up:

- Track 3
- Track 6
- Track 12
- Track ad hoc

For Other Actions:

- Track Dx
- Track Complete
- Track Amend

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Sample Tracker Phrases

Voice Command	Cryptic Phrase	Print out on CT looks like this:
Track 3	**(Track 3)**	**Reduced-dose Chest CT is recommended in 3 months**
Track 12	**(Track 12)**	**Reduced-dose Chest CT is recommended in 12 months**
Track Diagnostic	**(Track Dx)**	**Diagnostic studies such as PET-CT or tissue sampling are recommended. If such studies are not clinically indicated or feasible, reduced dose Chest CT is recommended in 3 months.**
Track Complete	**(Track Complete)**	**Further follow-up of the lung nodules(s) is not recommended at this time.**

IMPRESSION:

1. Mild emphysema compatible with smoking related lung disease.
2. 8.5 mm solid nodule in the left lower lobe. Recommend follow-up chest CT in 3 months.

LUNG NODULE RECOMMENDATION (**Track3**)(for NJH Patient Tracking System)
The recommendation for follow-up interval is based on Fleischner Society guidelines. Clinical indications may supersede the recommendations.

Recommend reduced-dose chest CT in 3 months.

Lung-RADS® Version 1.1

Assessment Categories Release date: 2019

Category Descriptor	Lung-RADS Score	Findings	Management	Risk of Malignancy	Est. Population Prevalence
Incomplete	**0**	Prior chest CT examination(s) being located for comparison Part or all of lungs cannot be evaluated	Additional lung cancer screening CT images and/or comparison to prior chest CT examinations is needed	n/a	1%
Negative No nodules and definitely benign nodules	**1**	No lung nodules Nodule(s) with specific calcifications: complete, central, popcorn, concentric rings and fat containing nodules	Continue annual screening with LDCT in 12 months	< 1%	90%
Benign Appearance or Behavior Nodules with a very low likelihood of becoming a clinically active cancer due to size or lack of growth	**2**	**Perifissural nodule(s)** *(See Footnote 11)* < 10 mm (524 mm^3) **Solid nodule(s):** < 6 mm (< 113 mm^3) new < 4 mm (< 34 mm^3) **Part solid nodule(s):** < 6 mm total diameter (< 113 mm^3) on baseline screening **Non solid nodule(s) (GGN):** <30 mm (<14137 mm^3) **OR** ≥ 30 mm (≥ 14137 mm^3) and unchanged or slowly growing **Category 3 or 4 nodules unchanged for ≥ 3 months**			
Probably Benign Probably benign finding(s) - short term follow up suggested; includes nodules with a low likelihood of becoming a clinically active cancer	**3**	**Solid nodule(s):** ≥ 6 to < 8 mm (≥ 113 to < 268 mm^3) at baseline **OR** new 4 mm to < 6 mm (34 to < 113 mm^3) **Part solid nodule(s)** ≥ 6 mm total diameter (≥ 113 mm^3) with solid component < 6 mm (< 113 mm^3) **OR** new < 6 mm total diameter (< 113 mm^3) **Non solid nodule(s)** (GGN) ≥ 30 mm (≥ 14137 mm^3) on baseline CT or new	6 month LDCT	1-2%	5%
Suspicious Findings for which additional diagnostic testing is recommended	**4A**	**Solid nodule(s):** ≥ 8 to < 15 mm (≥ 268 to < 1767 mm^3) at baseline **OR** growing < 8 mm (< 268 mm^3) **OR** new 6 to < 8 mm (113 to < 268 mm^3) **Part solid nodule(s):** ≥ 6 mm (≥ 113 mm^3) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm^3) **OR** with a new or growing < 4 mm (< 34 mm^3) solid component **Endobronchial nodule**	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component	5-15%	2%
Very Suspicious Findings for which additional diagnostic testing and/or tissue sampling is recommended	**4B**	**Solid nodule(s)** ≥ 15 mm (≥ 1767 mm^3) **OR** new or growing, and ≥ 8 mm (≥ 268 mm^3) **Part solid nodule(s) with:** a solid component ≥ 8 mm (≥ 268 mm^3) **OR** a new or growing ≥ 4 mm (≥ 34 mm^3) solid component	Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component. *For new large nodules that develop on an annual repeat screening CT, a 1 month LDCT may be recommended to address potentially infectious or inflammatory conditions*	> 15%	2%
	4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			
Other Clinically Significant or Potentially Clinically Significant Findings (non lung cancer)	**S**	**Modifier - may add on to category 0-4 coding**	As appropriate to the specific finding	n/a	10%

Lung RADS 4 Categories

Suspicious Findings for which additional diagnostic testing is recommended	4A	**Solid nodule(s):** ≥ 8 to < 15 mm (≥ 268 to < 1767 mm^3) at baseline OR growing < 8 mm (< 268 mm^3) OR new 6 to < 8 mm (113 to < 268 mm^3)	3 month LDCT; PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component	5-15%	2%
		Part solid nodule(s): ≥ 6 mm (≥ 113 mm^3) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm^3) OR with a new or growing < 4 mm (< 34 mm^3) solid component			
		Endobronchial nodule			
Very Suspicious Findings for which additional diagnostic testing and/or tissue sampling is recommended	4B	**Solid nodule(s)** ≥ 15 mm (≥ 1767 mm^3) OR new or growing, and ≥ 8 mm (≥ 268 mm^3)	Chest CT with or without contrast, PET/CT and/or tissue sampling depending on the *probability of malignancy and comorbidities. PET/CT may be used when there is a ≥ 8 mm (≥ 268 mm^3) solid component. *For new large nodules that develop on an annual repeat screening CT, a 1 month LDCT may be recommended to address potentially infectious or inflammatory conditions*	> 15%	2%
		Part solid nodule(s) with: a solid component ≥ 8 mm (≥ 268 mm^3) OR a new or growing ≥ 4 mm (≥ 34 mm^3) solid component			
	4X	Category 3 or 4 nodules with additional features or imaging findings that increases the suspicion of malignancy			

Lung Nodule Registry Process

- Registry is facility-built SQL database
- Imports Tracker phrases from radiology reports
- Determines patient's lung cancer risk (high or not high) based on EHR data
- Calculates due date for follow-up CT
- Generates monthly report of patients who are one month overdue for follow-up CT
- Reminder letter generated to patient with copy sent to referring provider

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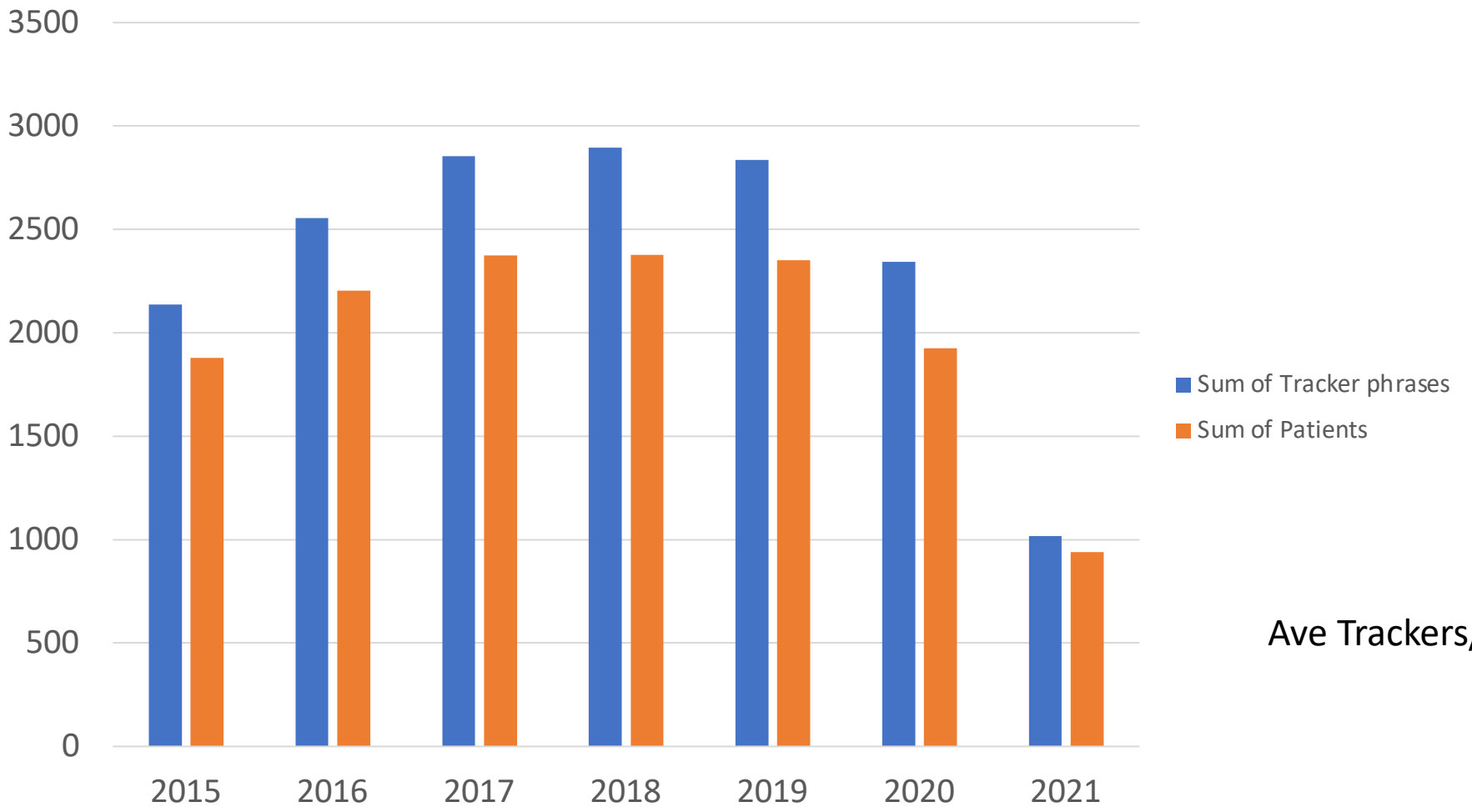
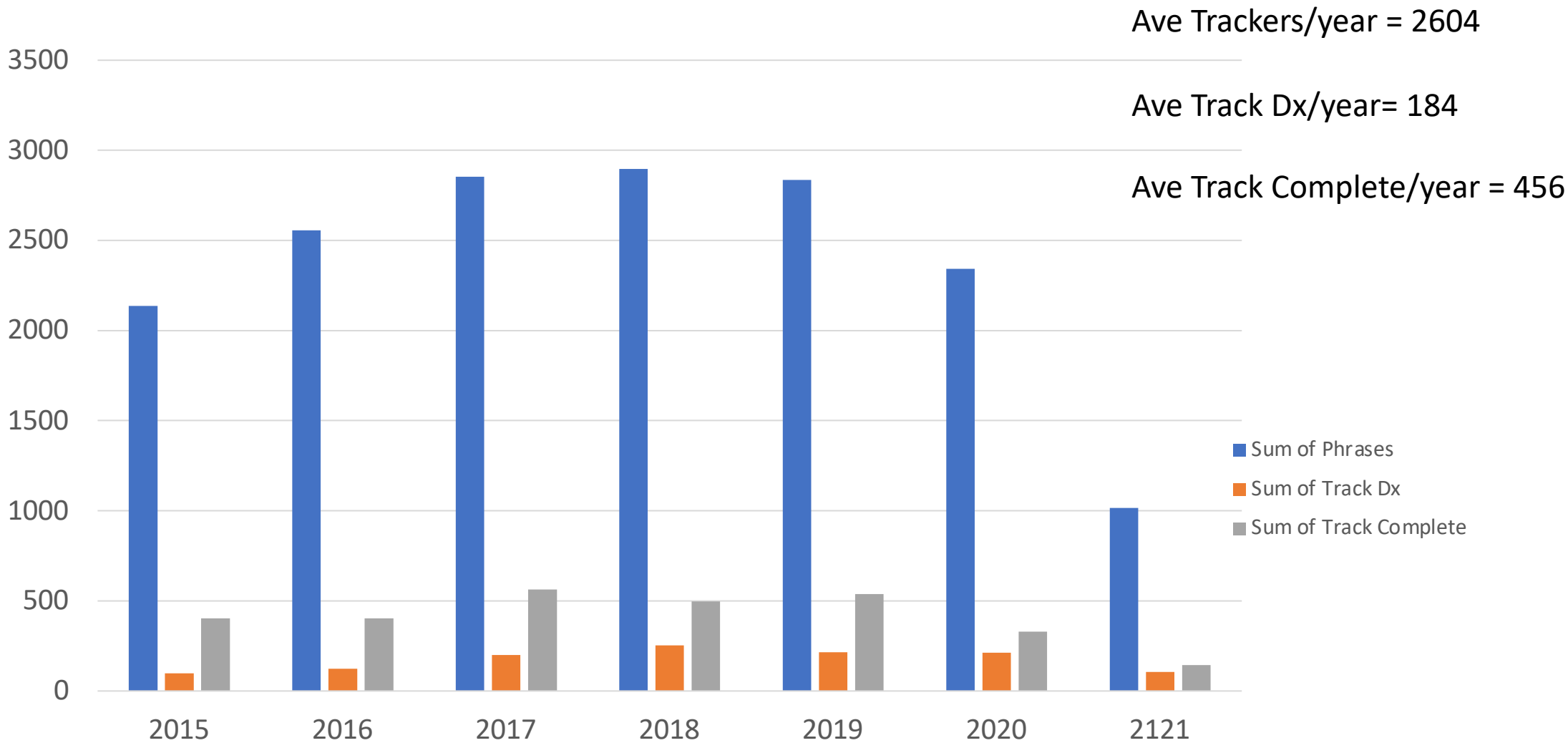
NJH Lung Nodule Registry



Ave Trackers/year = 2604

Track Dx and Track Complete



Track Dx

- The radiologists flag nodules as suspicious for malignancy with the use of “Track Dx”
- CTs assigned this phrase indicate the need for immediate work-up such as PET-CT, biopsy, or surgical referral
- The patients are automatically referred to weekly Multidisciplinary Suspicious Nodule Conference
- Approximately 30% of Track Dx nodules are diagnosed with lung cancer

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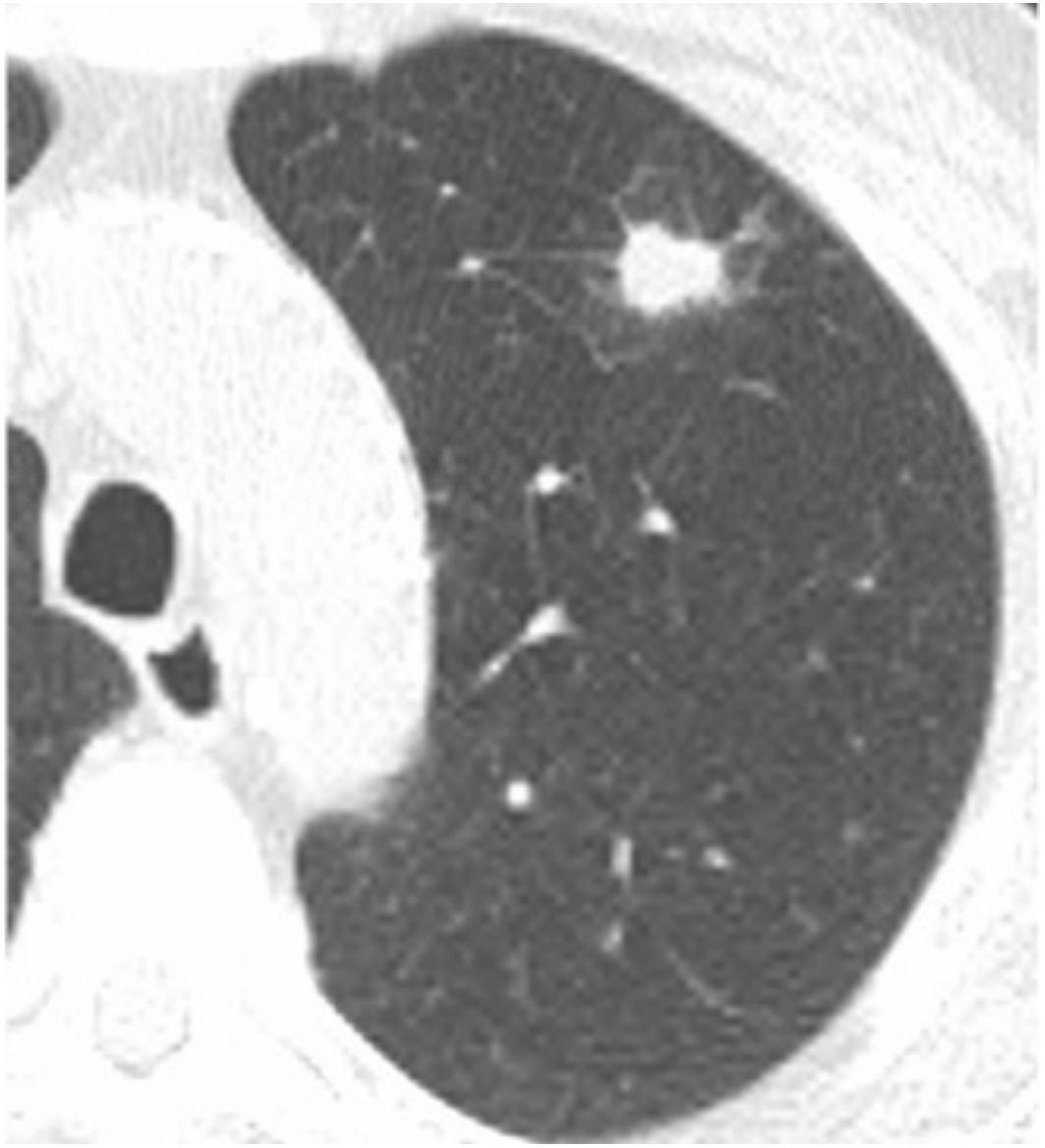
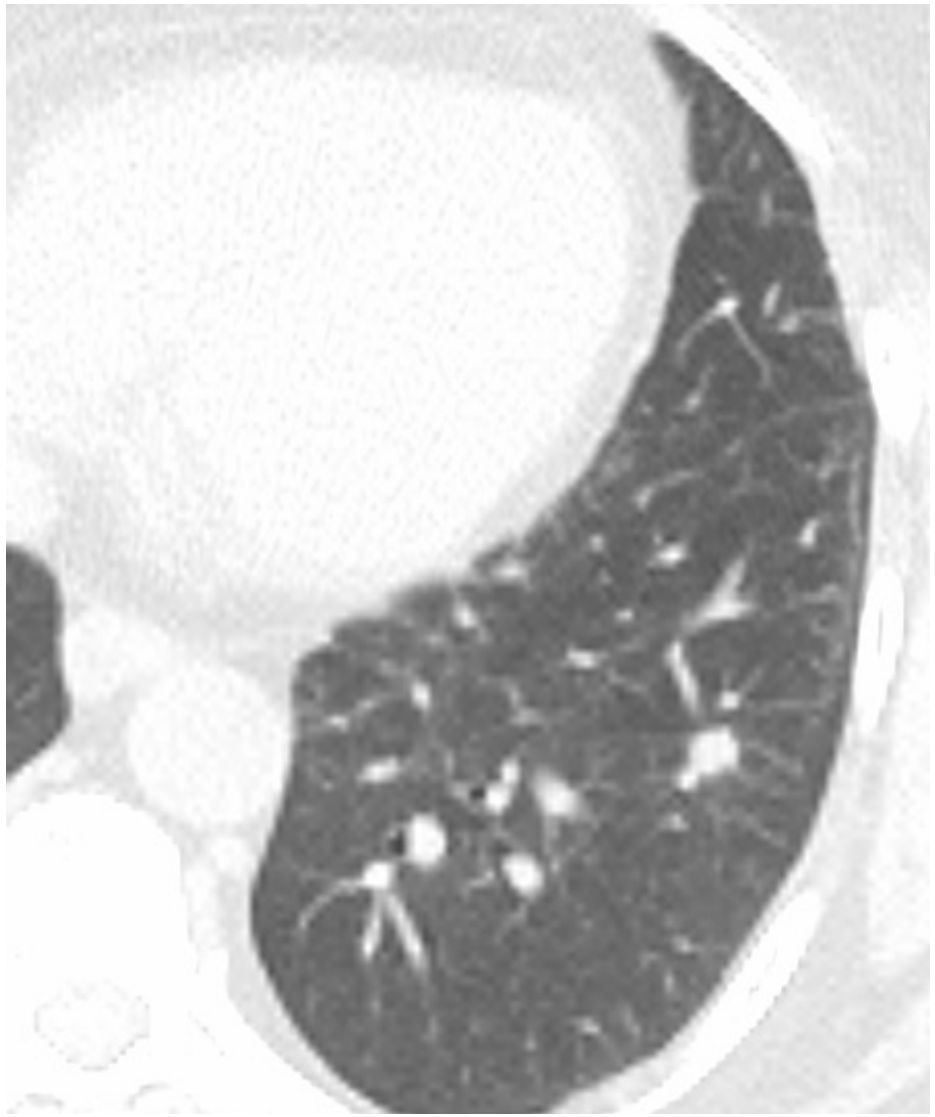
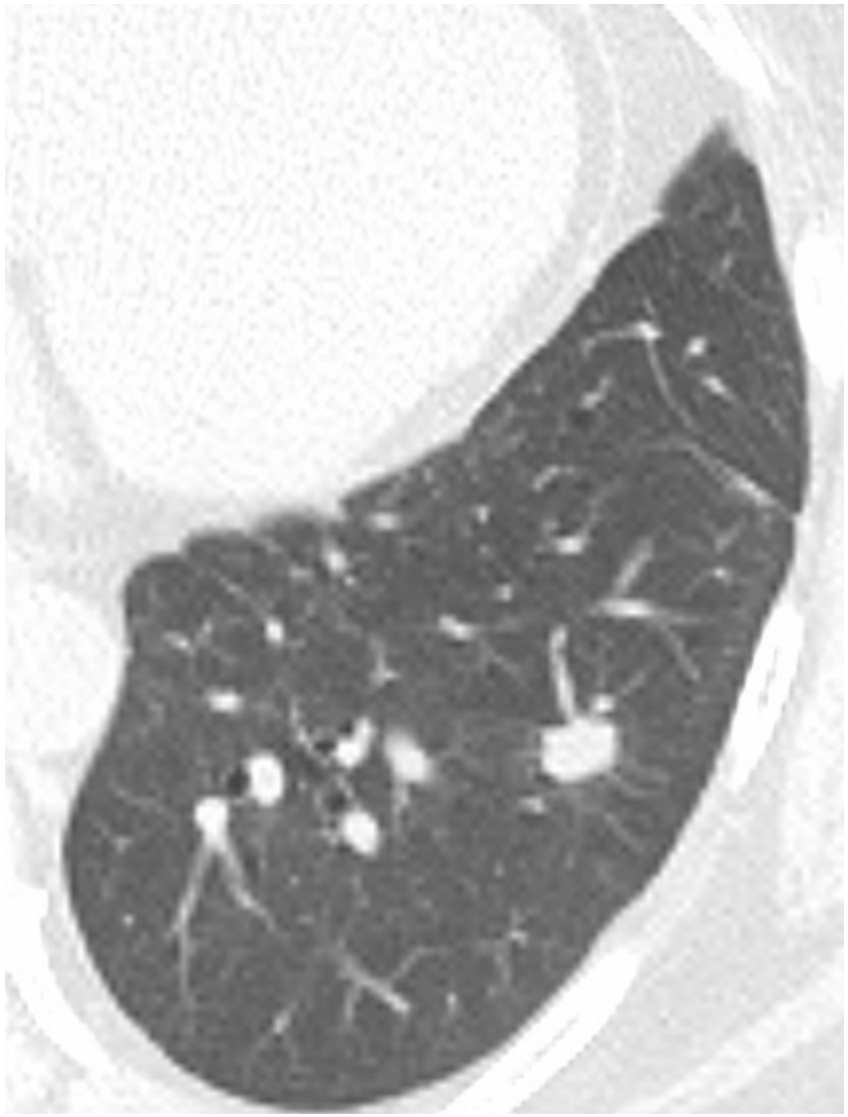
Example of a Track Dx Nodule



Track 12



12 months later
now Track Dx



Track Complete

- Radiologist can inactivate patients in the Registry when nodule resolves or remains stable by use of the “Track Complete” phrase
- This recommendation for “no further follow-up” saves health care resources and avoids unnecessary radiation exposure
- Approximately 20% of cases with Tracker phrases are “Track Complete” each year

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Track Amend

- The radiologist can amend the original CT report by adding a new Tracker phrase if:
  - Prior outside scans or information become available that change recommendation
  - Review of the case at Multidisciplinary Suspicious Nodule Conference results in a different recommendation for next step
- This allows the Registry to be updated and to continue to track the patient for needed follow-up

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The NJH Experience

- We found a 41% increase in timely follow-up after implementation of the Tracker Phrase System and Lung Nodule Registry
- The Tracker System has been used consistently by our radiologists since 2011 and has been easily adopted by new radiologists
- The addition of simple tracker phrases provide clear messaging in radiology reports that can imported into a Lung Nodule Registry
- The computerized registry allows patient follow-up to be tracked and automatic communication when exams are overdue.

Dyer et al, J Am Coll Radiol Feb 2021

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Impact of Tracking System on Stage of Lung Cancer

- Retrospective review of 937 cases of primary lung cancer, 2008 – 2016 with at least one chest CT performed at NJH
- Patient excluded if Lung Cancer Screening CT, if first and only CT resulted in immediate cancer diagnosis, if last chest CT > 2.5 years since cancer diagnosis
- Of 314 remaining patients with diagnosed with Lung Cancer, 200 were Early Stage (Stage I) and 114 were Later Stage (Stages II – IV or not staged)

Carr et al JTOCRR 2022

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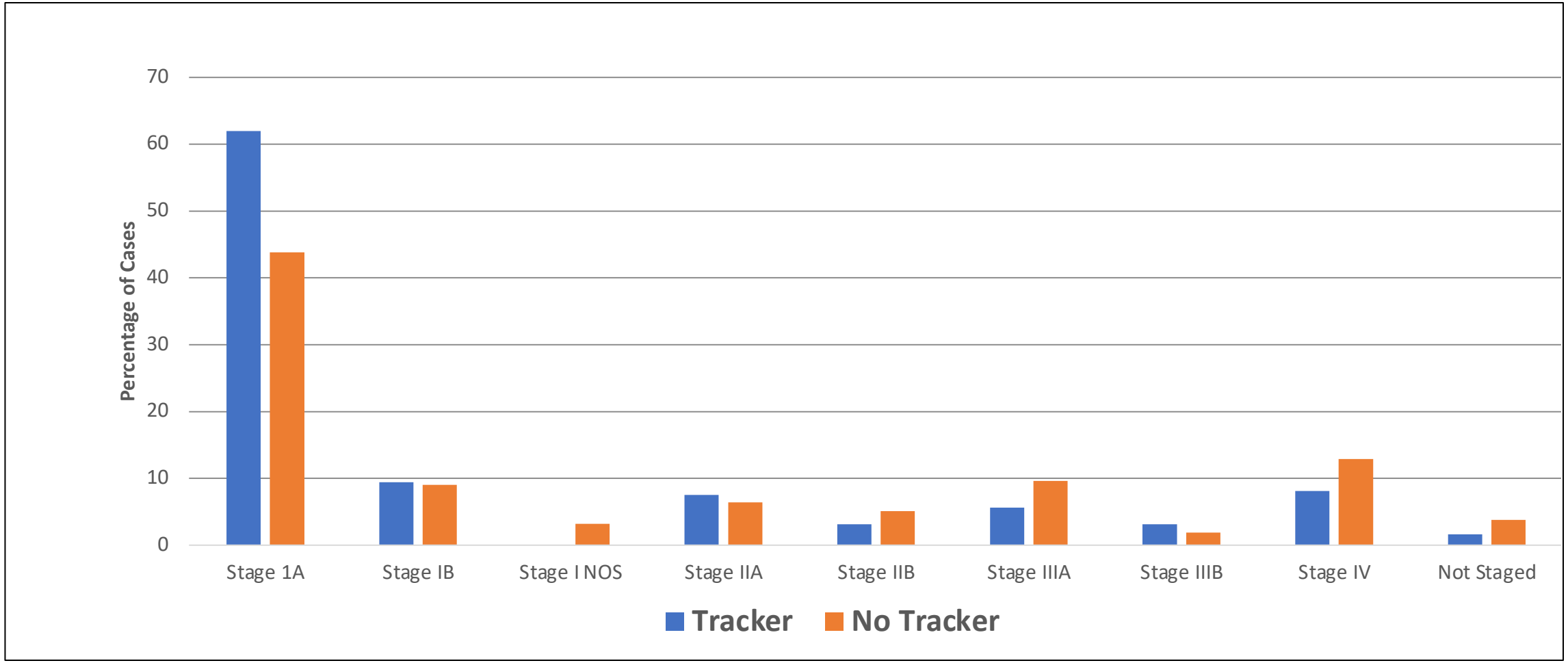
IPNs: Cancers by Stage, Tracker vs No Tracker



Weekly Post Nodule Conference Summary

LAST name	MRN	Date of Interpretation @ NJH	Date of Outside exam (if appropriate)	Lung RADS	Tracker Phrase	Size (mm)	Location	Tammi magi Risk %	Vancouver Probabil of Malig %	Referring Provider	Recommendation
XXXXXX	XXXXXXX	9/13/2021		4B		23	LLL	1.6	29.5	XXX	Rad rec: Tissue sampling Conf rec: CT-guided biospy
XXXXXX	XXXXXXX	9/9/2021		4A		10	RUL	1.3	13.5	XXX	Rad rec: Follow-up CT in 3 months Conf rec: Follow-up CT in 3 months
XXXXXX	XXXXXXX	9/9/2021		4X		27	LUL	5.5	36.6	XXX	Rad rec: Tissue sampling Conf rec: Referral to IP for Bronchoscopy
XXXXXX	XXXXXXX	9/8/2021		4B		15	RLL	3.9	32.4	XXX	Rad rec: Follow-up CT in 4-6 weeks Conf rec: Follow-up CT in 4-6 weeks
XXXXXX	XXXXXXX	9/13/2021	8/30/2021		Trackdx	9	RUL		16.4	XXX	Rad rec: PET/CT Conf rec: PET-CT and referral to IP
XXXXXX	XXXXXXX	9/9/2021	7/30/2021		Trackdx	17	LUL		59.3	XXX	Rad rec: Tissue sampling Conf rec: Follow-up CT in 3 months
XXXXXX	XXXXXXX	9/9/2021			Trackdx	14	LLL		9.5	XXX	Rad rec: Tissue sampling Conf rec: Referral to Rad Onc
XXXXXX	XXXXXXX	PET-CT 9/13/2021			Trackdx	15 (SUV 3)	LLL		16.6	XXX	Rad rec: Tissue sampling Conf rec: Referral to Thoracic Surgery

Summary

- While both IPN and LCS Programs can identify suspicious nodules, they differ significantly in strategy, resources and patient engagement
- Incidental Lung Nodules are common but follow-up is often variable or lacking
- An IPN Program is an important adjunct to LCS and essential for the Early Detection of Lung Cancer

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