Why IPN Programs are Needed Now More Than Ever

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FLASCO Early Lung Cancer Summit
January 21, 2023

Disclosures

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



Objectives

- 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

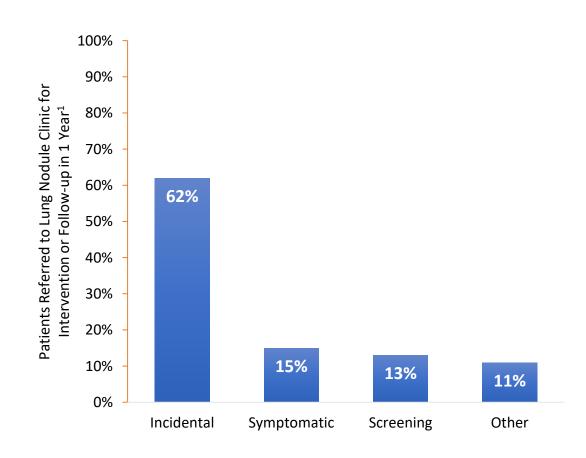


Why Now?

- Outlook for lung cancer has improved dramatically over the last 5 years due to screening and treatment advances
- Lung Cancer still remains the #1 cancer killer
- Identifying lung cancer earlier is cost effective
- Lung cancer screening only reaches a small part of the population
- More and more cancers are bring identified in people who have formerly smoked or never smoked
- We know how to manage lung nodules but need better systems in place for managing follow-up
- Clinicians are now more comfortable with the idea of follow-up CT and not immediate work-up
- Effective IPN Programs can result in stage shift to earlier stage lung cancers

The Majority of Lung Nodules Are Incidentally Detected¹

- 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 symptoms¹
 - 15% were found In patients with symptoms attributed to lung disease¹
 - 13% were identified in patients who qualified for annual LDCT screening^{1,2,b}



^{*} Retrospective analysis from a single-center, comprehensive lung nodule program at a community practice in Tennessee. Badults aged 55-80 years who have a 30-pack year smoking history and currently smoke or have quit within the past 15 years. Retropsective, observational study of chest CT imaging in KPSC, an integrated health care system, between 2006 and 201

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 Follow-up by Description of Incidental Nodule in



Approximately 2 out of 3 patients with incidentally detected pulmonary nodules receive no clinical follow-up¹⁻³

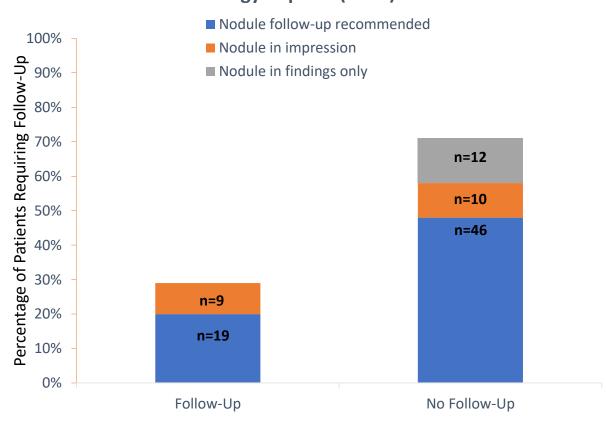


0% follow-up has been observed when incidental nodules are **mentioned only in the findings section** of the radiology report³



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

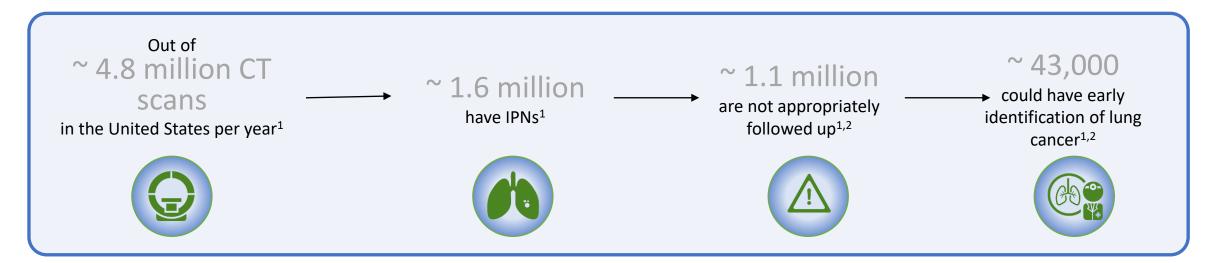
Follow-up by Description of Incidental Nodule in Radiology Reports (n=96)³



^{• 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.

Estimations Indicate That Improved Incidental Nodule Follow-Up Is Needed

- Based on the low rate of follow-up of incidental pulmonary nodules, we can estimate several lung cancer cases are missed at early-stage disease^{1,2}
- 41% of NSCLC cases are identified at Stage IV disease, with a 5-year survival rate between <1% and 10%, while Stage IA disease has an incidence of 14% and can have a 5-year survival rate of up to 92%^{3,4}



If follow-up was organized and consistent, more early-stage lung cancers could be identified

- CT, computed tomography; IPN, incidental pulmonary nodule; NSCLC, non-small cell lung cancer.
- 1. Gould MK, et al. Am J Respir Crit Care Med. 2015;192(10):1208-1214. 2. Blagev DP, et al. J Am Coll Radiol. 2014;11(4):378-383. 3. Heist RS, Engelman JA. Cancer Cell. 2012;21(3):448.e2. 4. Goldstraw P, et al. J Thorac Oncol. 2016;11(1):39-51.

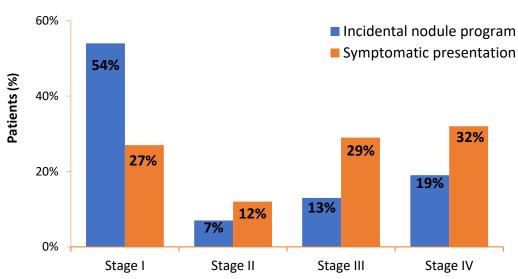
Follow-up of Patients With Incidental Nodule Findings Increases Early-Stage Diagnoses¹

Detection of **incidental nodules** on chest CT scans are common and **occur in** ≈30% of all scans²



Of an estimated **1.6 million patients with an incidental nodule** detected by chest CT scan in the US in 2010, >63,000 received a new lung cancer diagnosis within 2 years²

Incidental Nodule Program Increased the Rate of Stage I Lung Cancer Diagnosis vs Symptomatic Presentation^a (2016-2018)¹



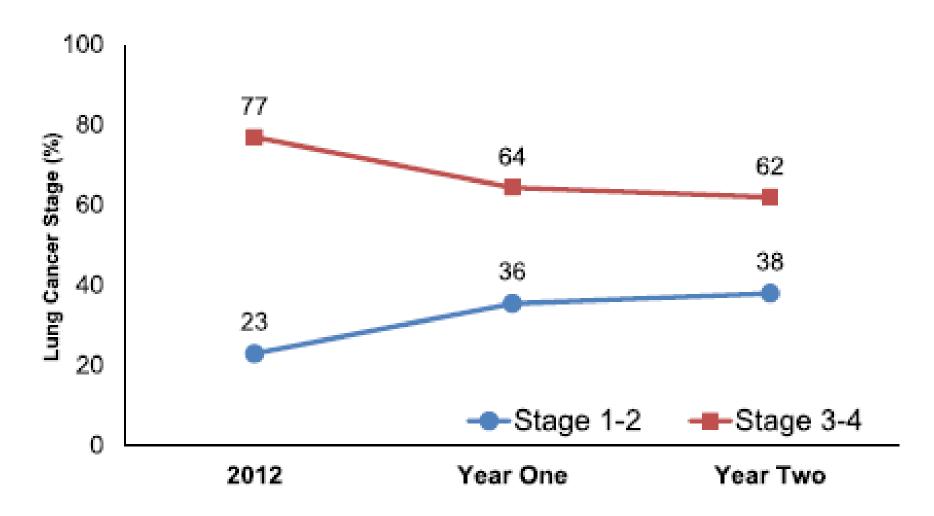
Robust management and follow-up of incidental nodules can lead to diagnosis of early-stage lung cancer in individuals who would not otherwise be considered high risk¹

^aSymptomatic patients evaluated by a multidisciplinary committee

CT, computed tomography; US, United States

^{• 1.} Unpublished data shared with permission. Multidisciplinary Thoracic Oncology Program, Baptist Memorial Healthcare, Memphis, TN. 2. Gould MK, et al. Am J Respir Crit Care Med. 2015;192(10):1208-1214.

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



IPN Programs

Advantages	Challenges
CT already done	Numerous referring providers including ER
No "Eligibility" criteria	No pre-imaging commitment to diagnosis and treatment
Routine Chest CTs and CTAs	Often no dedicated staff or resources
Very high volume performed	Need system for tracking follow-up
High yield due large volume	
Established guidelines available (Fleischner)	

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



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



Menu of Tracker Phrases based on 2017 Fleischner Society Guidelines

For CT Follow-up:

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

For Other Actions:

- Track Dx
- Track Complete
- Track Amend



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 Societyguidelines.
Clinical indications may supersede the recommendations.

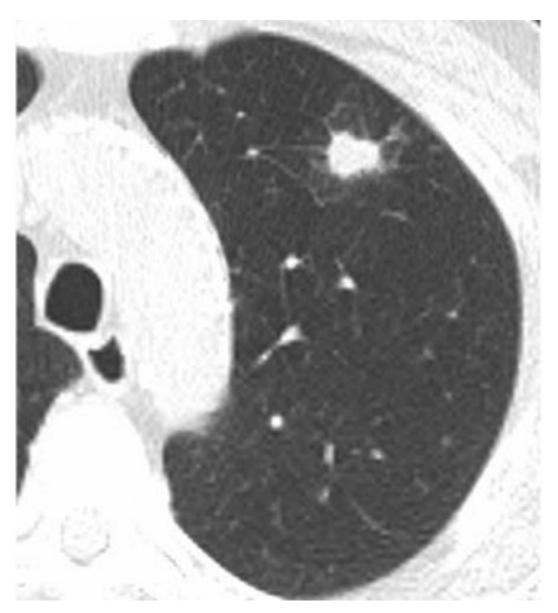
Recommend reduced-dose chest CT in 3 months.

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

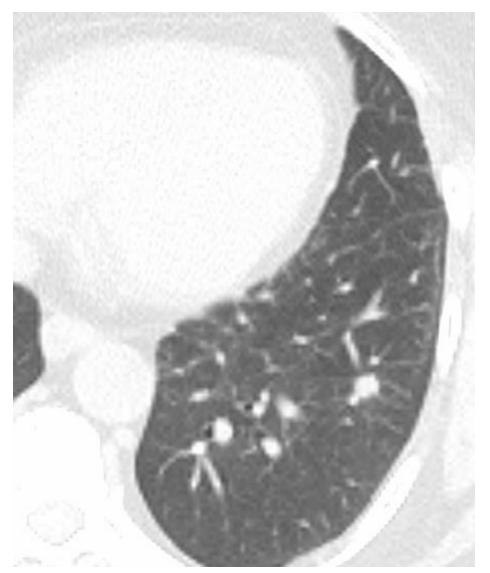


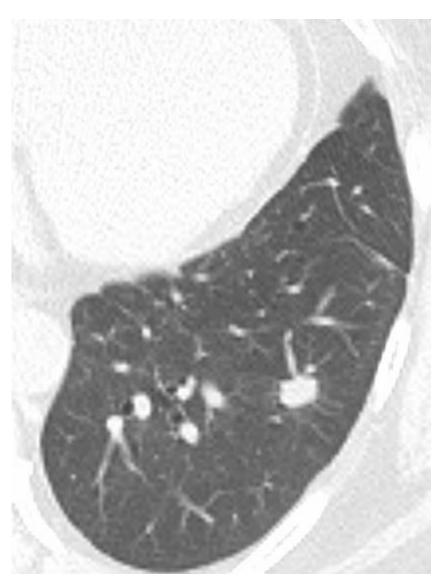
Track Dx Nodule



Track 12

12 months later now Track Dx



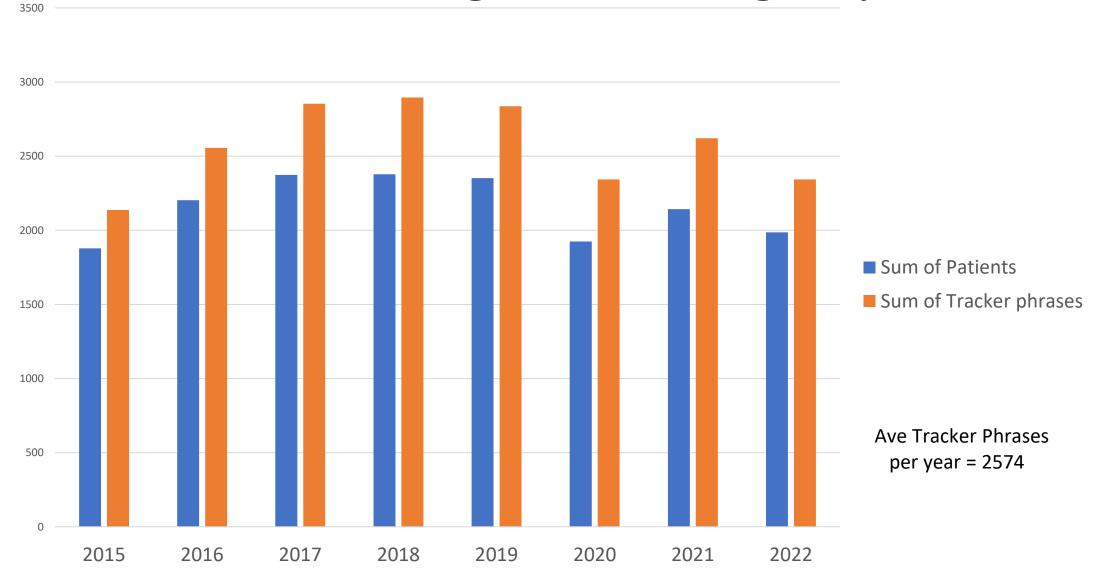


Track Complete

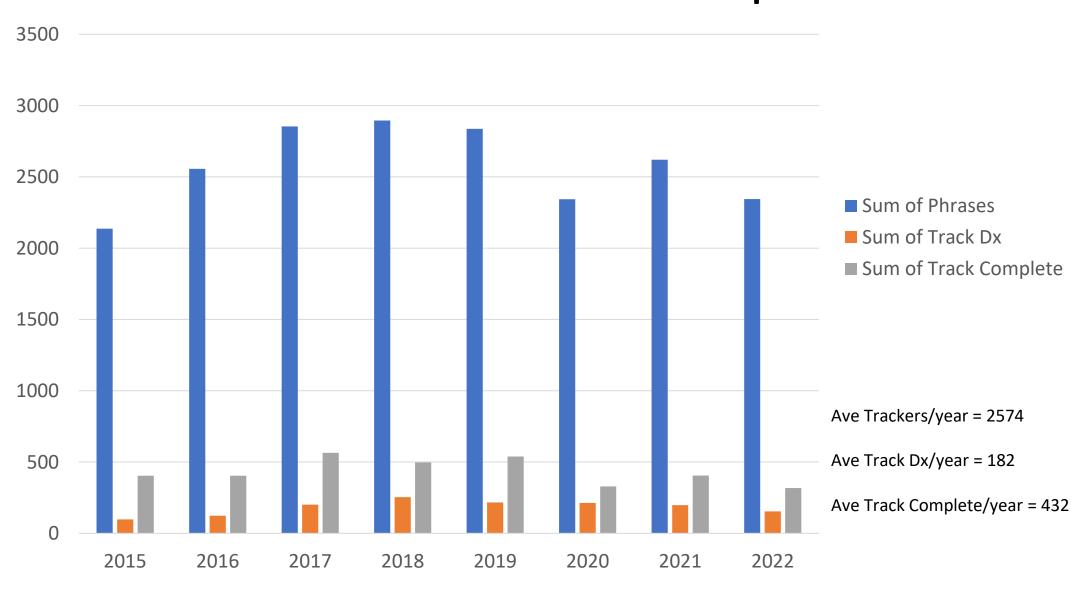
- Radiologist can inactivate patients in the Registry when nodule resolves or remains stable by use of the "Track Complete" phrase
- This recommendation for "no further follow-up" saves health care resources and avoids unnecessary radiation exposure
- Approximately 17% of cases with Tracker phrases are "Track Complete" each year



NJH Lung Nodule Registry



Track Dx and Track Complete



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.

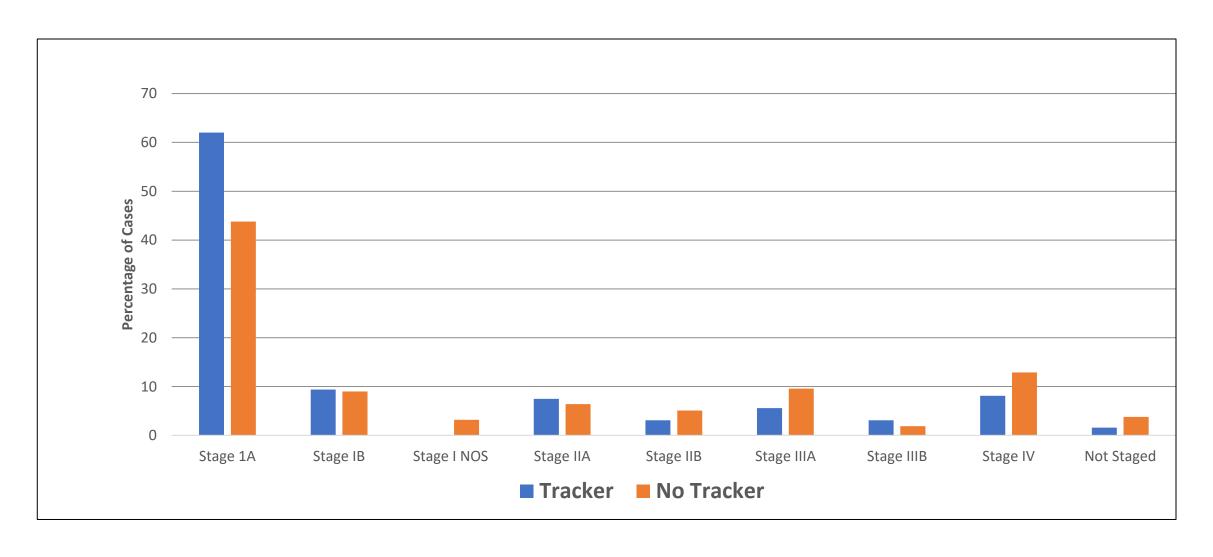


Impact of Tracking System on Stage of Lung Cancer

- 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)



IPNs: Cancers by Stage, Tracker vs No Tracker



Synergy with Lung Cancer Screening



Lung-RADS® 2022

Release Date: November 2022

Lung- RADS	Category Descriptor	Findings	Management	
		Prior chest CT examination being located for comparison (see note 9)	Comparison to prior chest CT;	
0	Incomplete Estimated Population Prevalence: ~ 1%	Part or all of lungs cannot be evaluated	Additional lung cancer screening CT imaging needed;	
		Findings suggestive of an inflammatory or infectious process (see note 10)	1-3 month LDCT	
	Negative	No lung nodules OR		
1	Estimated Population Prevalence: 39%			
	Benign Based on imaging features or indolent behavior Estimated Population Prevalence: 45%	Juxtapleural nodule: • < 10 mm (524 mm³) mean diameter at baseline or new AND • Solid; smooth margins; and oval, lentiform, or triangular shape		
		Solid nodule: • < 6 mm (< 113 mm³) at baseline OR • New < 4 mm (< 34 mm³)	- 12-month screening LDCT	
2		Part-solid nodule: • < 6 mm total mean diameter (< 113 mm³) at baseline		
		Non-solid nodule (GGN): • < 30 mm (< 14,137 mm³) at baseline, new, or growing OR • ≥ 30 mm (≥ 14,137 mm³) stable or slow-growing (see note 7)		
		Airway nodule, subsegmental at baseline, new, or stable (see note 11)		
		Category 3 nodule that is stable or decreased in size at 6-month follow-up CT, OR Category 3 or 4A nodules that resolve on follow-up, OR Category 4B findings proven to be benign in etiology following appropriate diagnostic workup		

LungRADS 1 & 2 "Negative" Screen

	Negative	No lung nodules OR	
1	Estimated Population Prevalence: 39%	Nodule with benign features: Complete, central, popcorn, or concentric ring calcifications OR Fat-containing	12-month screening LDCT
		Juxtapleural nodule: • < 10 mm (524 mm³) mean diameter at baseline or new AND • Solid; smooth margins; and oval, lentiform, or triangular shape	
	Panian	Solid nodule: • < 6 mm (< 113 mm³) at baseline OR • New < 4 mm (< 34 mm³)	
2	Benign Based on imaging features or indolent	ed on imaging ures or indolent • < 6 mm total mean diameter (< 113 mm³) at baseline	
_	Estimated Population Prevalence: 45%	Non-solid nodule (GGN): • < 30 mm (< 14,137 mm³) at baseline, new, or growing OR • ≥ 30 mm (≥ 14,137 mm³) stable or slow-growing (see note 7)	
		Airway nodule, subsegmental at baseline, new, or stable (see note 11)	
		Category 3 nodule that is stable or decreased in size at 6-month follow-up CT, OR Category 3 or 4A nodules that resolve on follow-up, OR Category 4B findings proven to be benign in etiology following appropriate diagnostic workup	

LungRADS 3 "Positive" Screen

3	Probably Benign Based on imaging features or behavior Estimated Population Prevalence: 9%	Solid nodule: • ≥ 6 to < 8 mm (≥ 113 to < 268 mm³) at baseline OR • New 4 mm to < 6 mm (34 to < 113 mm³) Part-solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm³) with solid component < 6 mm (< 113 mm³) at baseline OR • New < 6 mm total mean diameter (< 113 mm³) Non-solid nodule (GGN): • ≥ 30 mm (≥ 14,137 mm³) at baseline or new	6-month LDCT
		Atypical pulmonary cyst: (see note 12) Growing cystic component (mean diameter) of a thick-walled cyst	
		Category 4A nodule that is stable or decreased in size at 3-month follow-up CT (excluding airway nodules)	

LungRADS 4 "Positive" Screen

4A	Suspicious Estimated Population Prevalence: 4%	Solid nodule: • ≥ 8 to < 15 mm (≥ 268 to < 1,767 mm³) at baseline OR • Growing < 8 mm (< 268 mm³) OR • New 6 to < 8 mm (113 to < 268 mm³) Part-solid nodule: • ≥ 6 mm total mean diameter (≥ 113 mm³) with solid component ≥ 6 mm to < 8 mm (≥ 113 to < 268 mm³) at baseline OR • New or growing < 4 mm (< 34 mm³) solid component Airway nodule, segmental or more proximal at baseline or new (see note 11) Atypical pulmonary cyst: (see note 12) • Thick-walled cyst OR • Multilocular cyst at baseline OR • Thin- or thick-walled cyst that becomes multilocular	3-month LDCT; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm³) solid nodule or solid component
4B	Very Suspicious Estimated Population Prevalence: 2%	Airway nodule, segmental or more proximal, and stable or growing (see note 11) Solid nodule: • ≥ 15 mm (≥ 1767 mm³) at baseline OR • New or growing ≥ 8 mm (≥ 268 mm³) Part-solid nodule: • Solid component ≥ 8 mm (≥ 268 mm³) at baseline OR • New or growing ≥ 4 mm (≥ 34 mm³) solid component Atypical pulmonary cyst: (see note 12) • Thick-walled cyst with growing wall thickness/nodularity OR • Growing multilocular cyst (mean diameter) OR • Multilocular cyst with increased loculation or new/increased opacity (nodular, ground glass, or consolidation) Slow-growing-solid or part-solid nodule that demonstrates growth over multiple screening exams (see note 8)	Referral for further clinical evaluation Diagnostic chest CT with or without contrast; PET/CT may be considered if there is a ≥ 8 mm (≥ 268 mm³) solid nodule or solid component; tissue sampling; and/or referral for further clinical evaluation Management depends on clinical evaluation, patient preference, and the probability of malignancy (see note 13)
4X	Estimated Population Prevalence: < 1%	Category 3 or 4 nodules with additional features or imaging findings that increase suspicion for lung cancer (see note 14)	

Weekly Nodule Conference Summary

LAST name	MRN	•	Date of Outside exam (if appropriate)	Lung RADS	Tracker Phrase	Size (mm)	Location	magi	Vancouver Probabil of Malig %	_	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	s 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)			16.6	s xxx	Rad rec: Tissue sampling Conf rec: Referral to Thoracic Surgery

Summary

- Incidental Lung Nodules are common but follow-up is often variable or lacking
- Appropriate management of IPNs through an IPN Program can lead to a stage shift to early stage lung cancer
- An IPN Program is an important adjunct to LCS and essential for the Early Detection of Lung Cancer

