

National Lung Cancer Screening Program Croatia

Population: 4 million

Accredited centers: 16 centers in 11 cities

*Equity, excellence and innovation – modern cancer care
for all. Europe's Beating Cancer Plan – eradicating
inequalities within cancer care*

Stockholm, February 2023

NELSON Trial



Randomized Controlled Trial

Recruitment through population-based registries

CT screening vs. no screening

Different screening intervals

Volume & Volume Doubling Time of nodules

Central reading of CT images

Expert causes of death committee &

Follow up through national registries

Trial, initially powered (80%) for high risk **males**, to detect a lung cancer mortality reduction of $\geq 25\%$ at 10 years after randomization (individual FU).

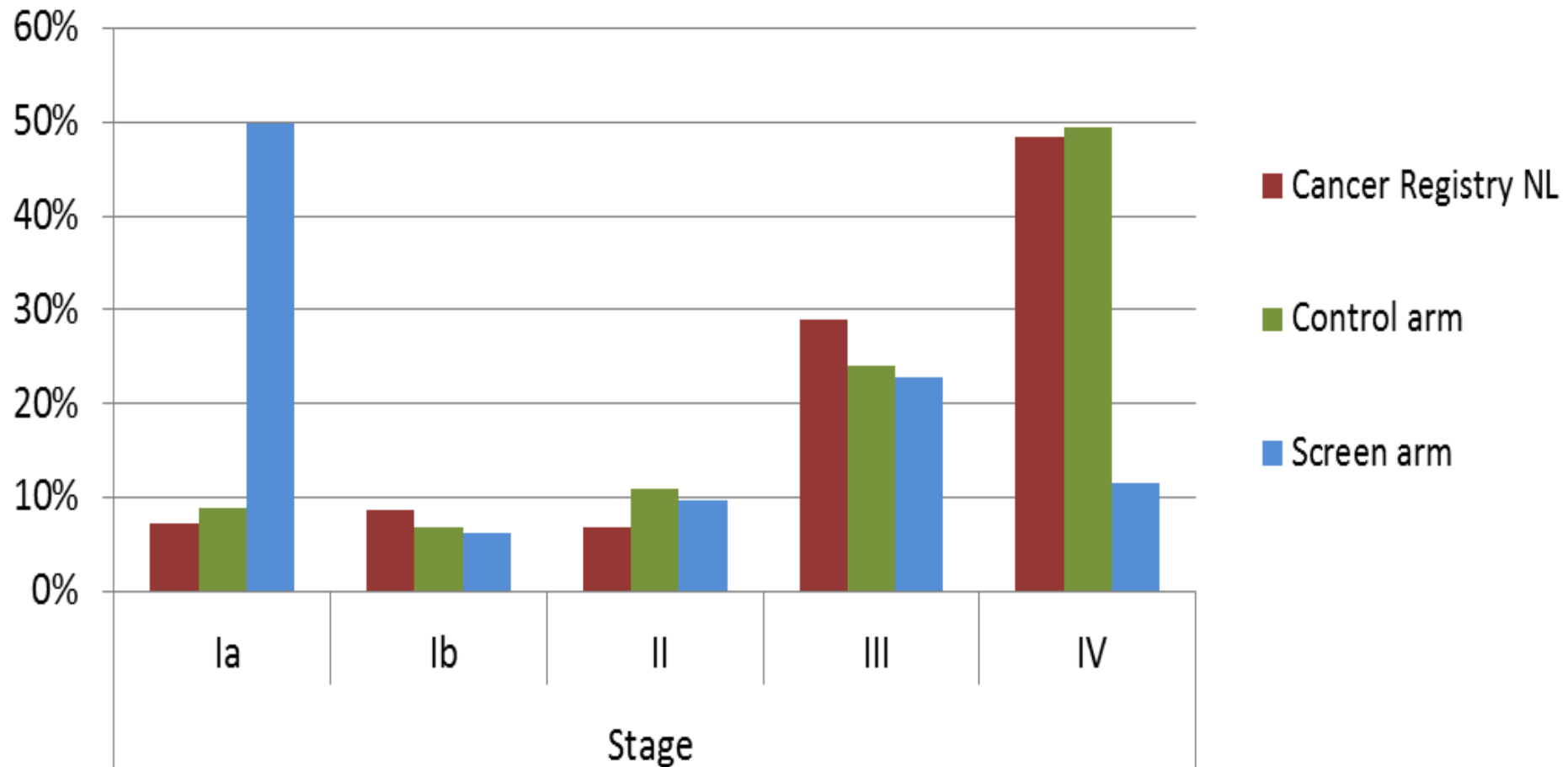
And includes a small subgroup of women (16%)

Lung cancer mortality rate ratio (95% CI)	Year 8	Year 9	Year 10
	<p>0.75</p> <p>P=0.015 (0.59-0.95)</p>	<p>0.76</p> <p>P=0.012 (0.60-0.95)</p>	<p>0.74</p> <p>P=0.003 (0.60-0.91)</p>
	<p>0.39</p> <p>P=0.0037 (0.18-0.78)</p>	<p>0.47</p> <p>P=0.0069 (0.25-0.84)</p>	<p>0.61</p> <p>P=0.0543 (0.35-1.04)</p>

Lung Cancer Stage (males NL) 7th TNM

Cancer Registry NL - Control Arm - Screen Arm

up to December 2011



Inclusion criteria

- Population at risk of both genders aged 50 – 75 years
- Currently smokers or have quit within the past 15 years
- Have at least a 30-pack-year smoking history
- Have been involved in **informed/shared decision** making about the benefits, limitations, and harms of screening with LDCT scans

Receive smoking cessation counseling if they are current smokers (brochure or scs)

Main Components of the Program

- i-ELCAP Guidelines (International Early Lung Cancer Action Program)
- Volumetric Analysis
- Artificial Intelligence
- GP based Strategy
- Digitalization

i-ELCAP Guidelines

Modified i-ELCAP

BASELINE LDCT	RECOMMENDATION
NEGATIVE - If there are NO noncalcified nodules	Return for first annual screening in 12 months
SEMI-POSITIVE (1) - Only nonsolid nodules are present, they can be of any size; Largest solid NCN < 6.5 mm or largest solid component of a part-solid NCN < 6.5 mm	Return for first annual screening in 12 months
SEMI-POSITIVE (2) - Largest NCN is solid ≥ 6.5 mm in average diameter OR largest NCN is part-solid and the solid component ≥ 6.5 mm in average diameter , but < 15.5 mm	Return for LDCT in three months
SEMI-POSITIVE (3) - Endobronchial solid any size	Return for LDCT in one month
POSITIVE - Largest solid NCN ≥ 15.5 mm	Referral to screening pulmonologist/nodule clinic

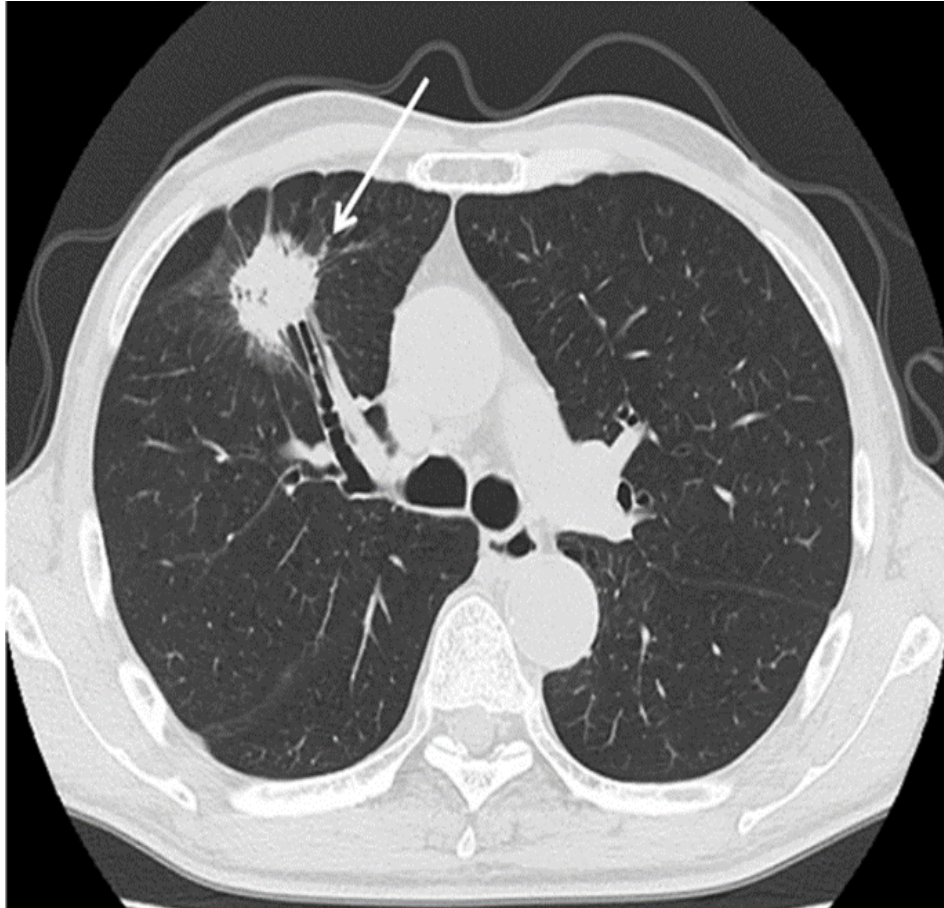
Volumetric Analysis

Artificial Intelligence

Modified i-ELCAP

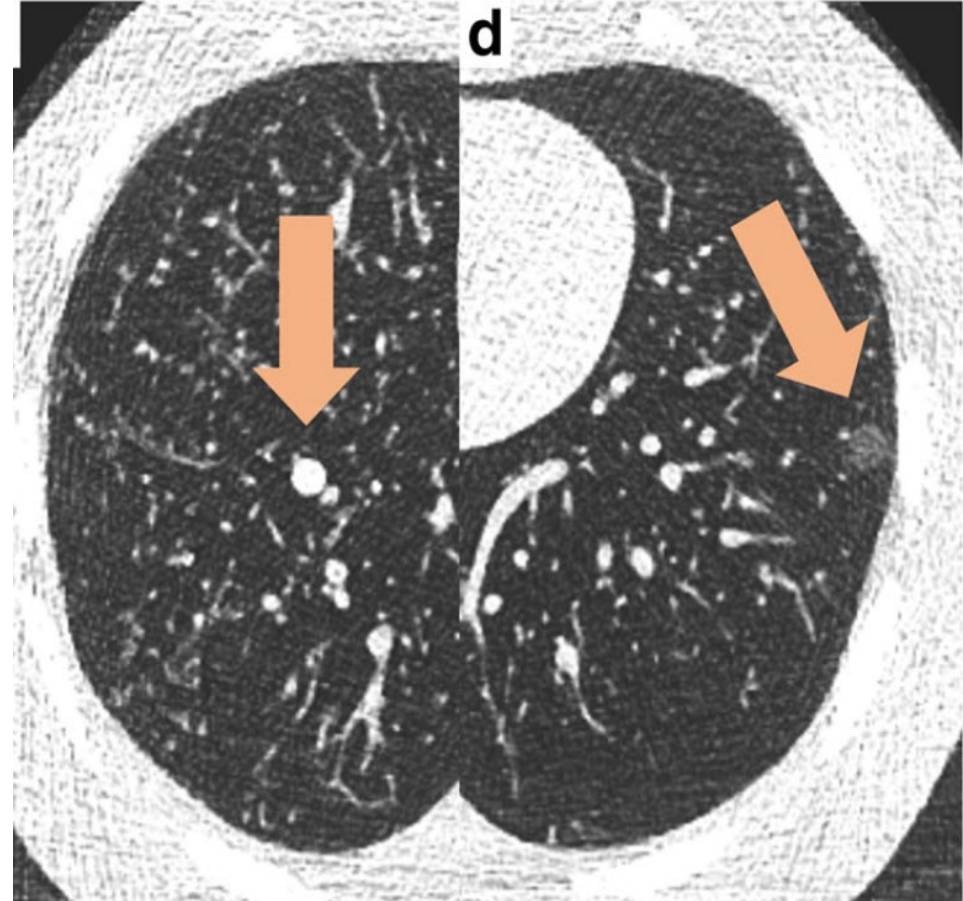
FOLLOW-UP LDCT	RECOMMENDATION
NEGATIVE - Nodule resolved	Next annual repeat screening in 24 months
SEMI-POSITIVE - VDT\geq600 days	Return for next annual repeat LDCT screening at 12 months from baseline (annual screening)
SEMI-POSITIVE - VDT 400 – 600 days	Return for 1st repeat LDCT screening in 6 months, if growth at the same rate repeat CT in 12 months
POSITIVE -VDT<400 days; Persistent endobronchial nodule	Referral to screening pulmonologist/nodule clinic
POSITIVE - VDT 400 – 600 days	When larger than 15 mm (2000 mm³) refer to screening nodule/pulmonology clinic

STANDARD CT



effective dose: 5 mSv
tube voltage: 120 kVp
tube current: 150 mAs

Ultra LOW DOSE



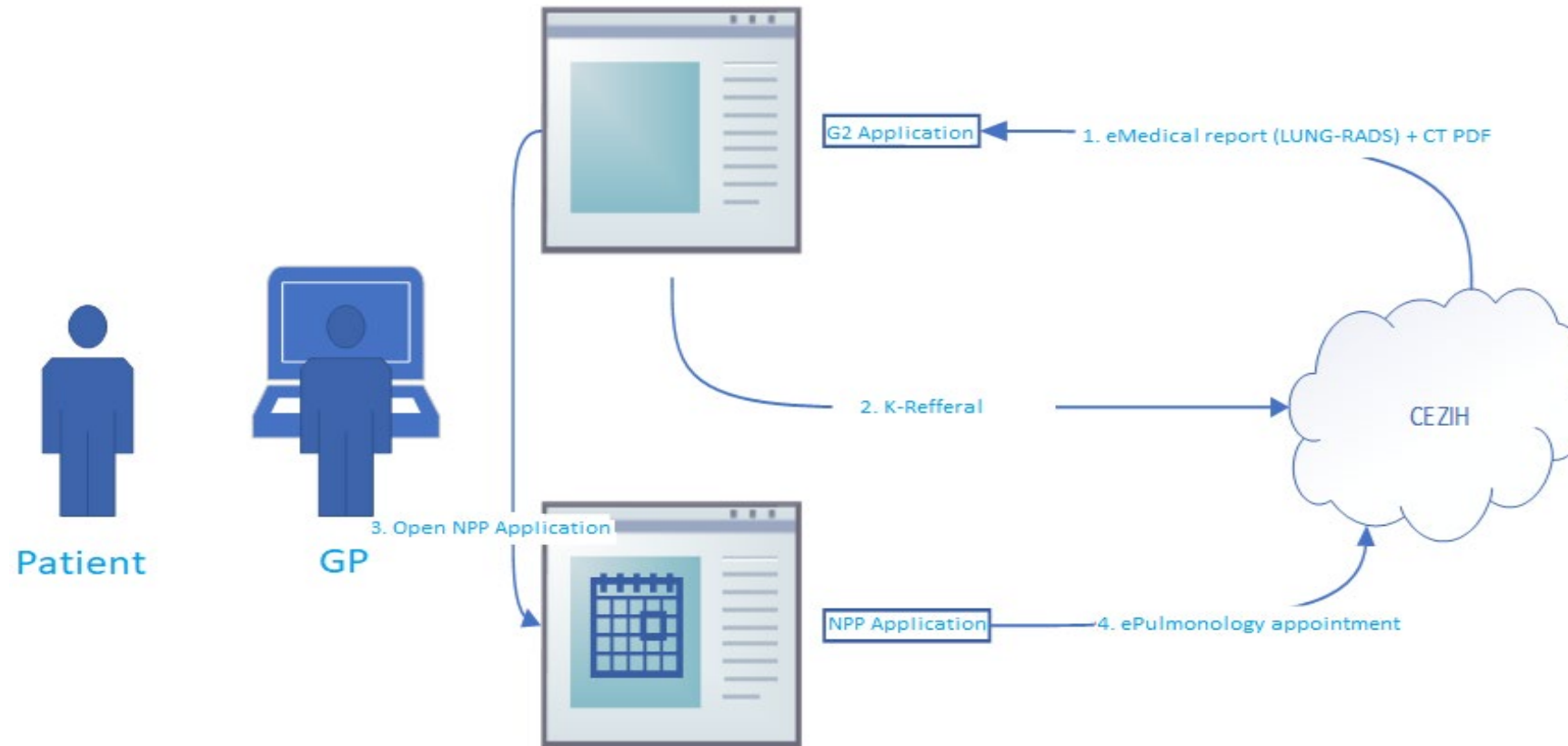
effective dose: 0.135 mSv
tube voltage: 80 kVp
tube current-time product: 6 mAs

Artificial intelligence

GP based Strategy

Digitalization

GP to radiologist CT scan result to GP GP to pulmonologist - surgeon



Croatian National Lung Cancer Screening Program Results

October 2020 – January 2023	Total (Scans)	Negative Findings	Semi-positive Findings	Positive Findings	Confirmed malignant disease (Participants)	Effective Radiation Dose
Total	13113 Baseline 11393 Follow up 1720 Male 55,45% Female 44,55% Average age 63	5403 (41,21%) No nodules	1407 (10,7%) Volume 150 - 2000mm ³ Diameter 6.5 - 15.5mm	504 (3,84%) Volume ≥2000mm ³ Diameter ≥15.5mm 161 (1,27%) VDT < 400 days	134 (1,17%) 120 Lung ca 100 adenocarcinoma 18 squamous 2 small cell 14 Other tumors 1 breast 2 kidney 1 colon 3 rectal 1 urothelial 1 non-Hodgkin 2 carcinoid 1 hamartoma 1 osteosarcoma 1 pleomorpha tumor	0,9 mSv Average value

Croatian National Lung Cancer Screening Program Results – Surgical Procedures

October 2020 – January 2023	Patients who underwent surgery	Patients not eligible for surgery	Patients waiting for surgery
Total	<p>64</p> <p>55 Lung ca</p> <p>Stage IA – 20 Stage IB – 12 Stage IC – 2 Stage IIA – 11 Stage IIB – 2 Stage IIIA – 6 Stage IIIC – 2</p> <p>9 Other tumors</p> <p>1 breast 1 kidney 2 rectal 2 carcinoid 1 hamartoma 1 osteosarcoma 1 pleomorpha tumor</p>	<p>65</p> <p>60 Lung ca</p> <p>Stage IV - 42 Stage IIIA – 3 Stage IIIB – 7 Stage IIIC - 6 SBRT - 2</p> <p>5 Other tumors</p> <p>1 colon 1 rectal 1 urothelial 1 non-Hodkgin 1 kidney</p>	<p>5</p>

Future tasks

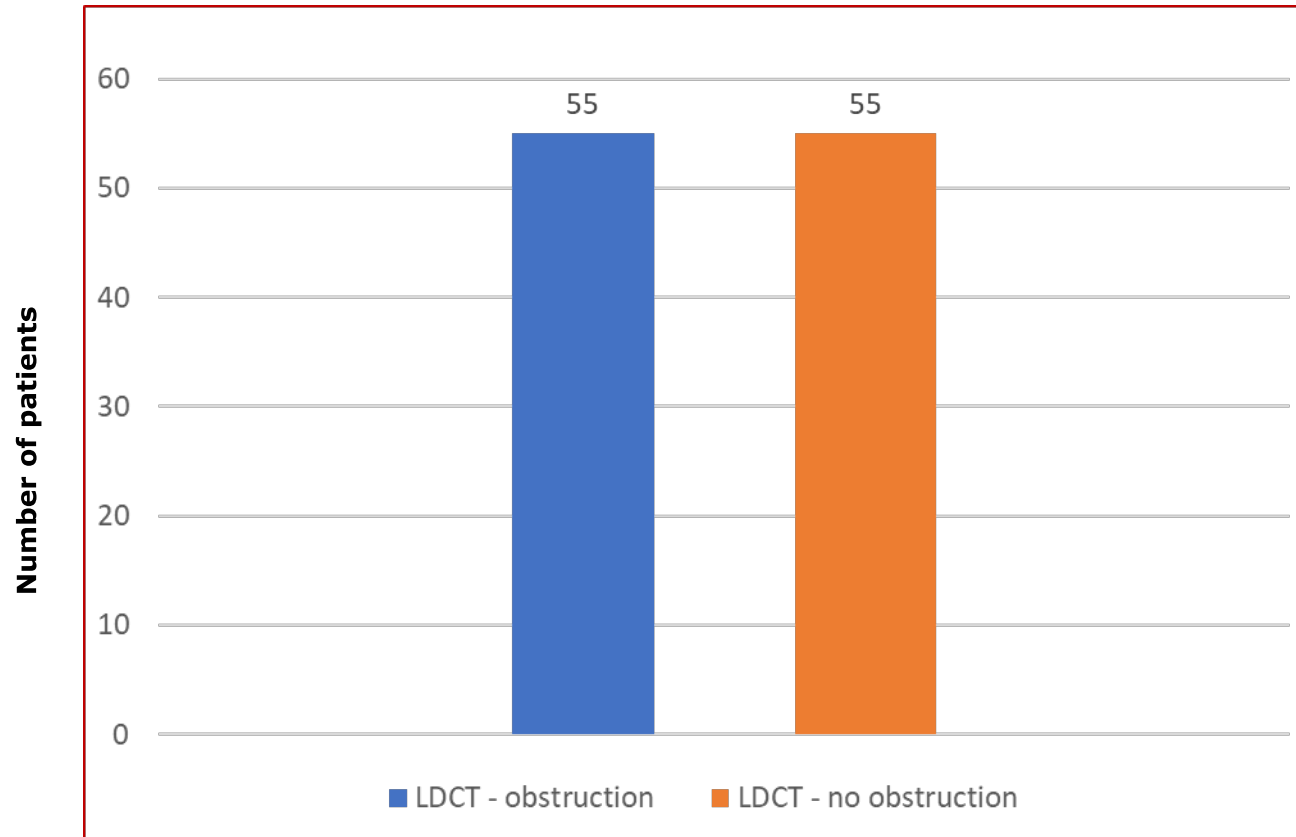
- **Lung Nodule Clinic**
- **Info Desk** at Clinic for Respiratory Diseases Jordanovac
- **Department of Psychology** within Lung Cancer Screening Program

- **Extend Screening Program** to other organs (Thyroid, **COPD**, Coronary Artery Disease, Liver)
- Scientific Projects:
 1. Proteomics
 2. Genome Analysis

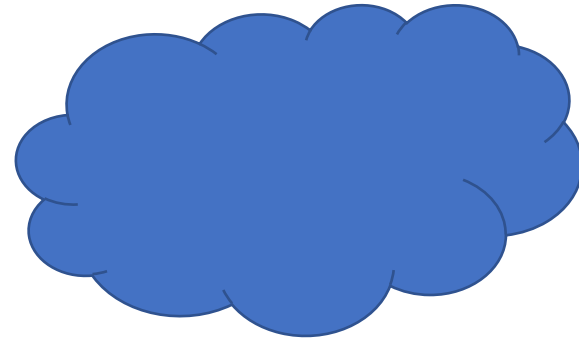
Patients with LDCT Emphysema and COPD (N=300)

Yes - 55 (19 %)

No - 55 (19 %)



**Data Base Storage
Radiation Burden Monitoring
Reports
External Quality Control
Scientific projects**



Cloud Storage

Start Day : October 2020