16th CONGRESS Lung ON CANCER

BARCELONA 27 / 28 NOVEMBER 2025

GECP lung cancer research

SLCG studies: Early stages NSCLC

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Medical Oncology Department

Salamanca University Hospital

GECP
lung cancer research

CONFLICT OF INTEREST

- The main author has received non-financial and educational support from Merck, MSD, Roche, Pfizer, Leo-Pharma, Rovi, Sanofi, Fresenius-Kabi, Ordesa, Persan, Ferrer, Astra-Zeneca y GSK.
- Principal investigator in privately funded clinical trials: GSK, Novartis.
- Research funding (Salamanca University Hospital): BMS.
- Advisor Board: Roche.

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- Active studies in recruitment or planned to start

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- Scientific activity in 2025

OVERVIEW OF ACTIVE STUDIES

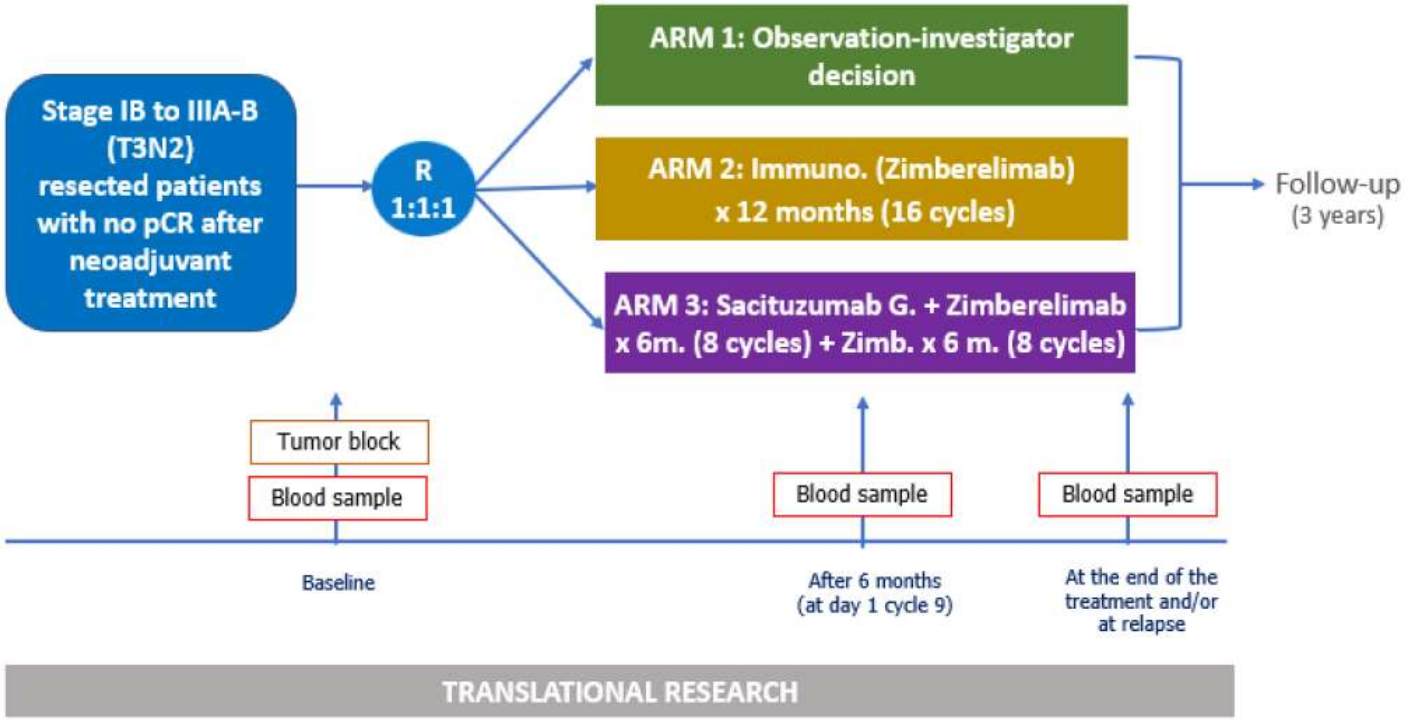
Active studies in recruitment or planned to start

Early and locally advanced stages

- **ARIAN**
  - Adjuvant post-neoadjuvant in IB-IIIB(N2) pts without pCR.
- **ARCH**
  - Adjuvant post-surgery in pts who have not received prior adjuvant CT.
- **ATHENEA**
  - Neoadjuvant stage IIIA/B with CT-atezolizumab and after surgery or CT/RT
- **MERIT-lung**
  - Induction with Sotorasib in stage III unresectable.
- **MIGRANT**
  - Fecal microbiota transplant in stage II-III prior neoadjuvant.

ARIAN

A phase III clinical trial of adjuvant treatment with Sacituzumab and Zimberelimab for stage IB-IIIA-IIIB(N2) previously resected (R0) non-small cell lung cancer (NSCLC) patients that do not achieve pathological complete response after neoadjuvant treatment.



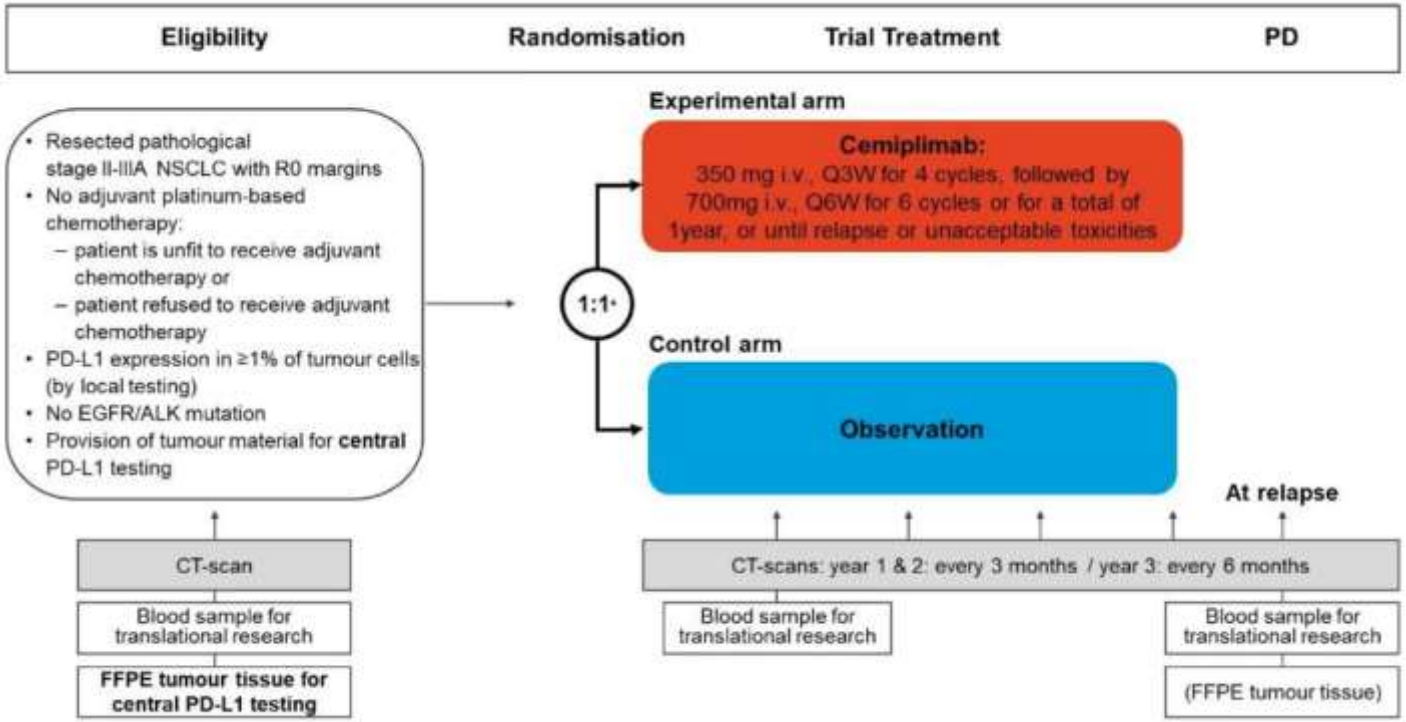
Nº	HOSPITAL	IP	FECHA APERTURA	SCREENING	INCLUIDOS	NO VALIDOS	VALIDOS
074	H. U. Dr. Negrín	Dr. Aguiar	04/FEB/2025	2	2	0	2
051	H. C. U. Valladolid	Dr. López	18/MAR/2025	2	2	0	2
058	H. U. Sant Joan de Reus	Dr. Lucía	25/FEB/2025	2	2	0	2
063	H. U. Salamanca	Dr. Olivares	21/MAR/2025	2	1	0	1
024	H. U. Son Espases	Dr. Aukbrate	25/FEB/2025	2	1	0	1
017	H. Clínico U. de Valencia	Dr. Irne	03/MAR/2025	2	1	0	1
037	C. A. U. León	Dr. Medina	04/APR/2025	1	1	0	1
015	H. Teresa Herrera	Dr. García	25/FEB/2025	1	1	0	1
007	H. Fund. Jiménez Díaz	Dr. Dolmane	25/FEB/2025	1	1	0	1
129	H. Santa María Nai	Dr. Arnoso	25/FEB/2025	1	1	0	1
055	H. U. Ntra. Sra. Candelaria	Dr. Medina	25/FEB/2025	2	0	0	0
011	H. Clínic de Barcelona	Dr. Reguart	21/MAR/2025	1	0	0	0
001	H. G. U. Dr. Balmis	Dr. Massuti	03/APR/2025	1	0	0	0
002	ICO Badalona	Dr. Domenech	29/MAY/2025	1	0	0	0
005	H. Puerta de Hierro	Dr. Provencio	25/FEB/2025	1	0	0	0
022	H. U. Son Llátzer	Dr. Coves	25/FEB/2025	-	-	-	-
040	C. C. S. Parc Taulí	Dr. Vilà	25/FEB/2025	-	-	-	-
072	H. U. Lucus Augusti	Dr. Campos	25/FEB/2025	-	-	-	-
157	C. H. U. Vigo	Dr. Lázaro	25/FEB/2025	-	-	-	-
053	H. U. Virgen del Rocío	Dr. Bernabé	25/FEB/2025	-	-	-	-
127	H. U. Jerez de la Frontera	Dr. Morano	25/FEB/2025	-	-	-	-
010	H. Santa Creu i Sant Pau	Dr. Bertó	27/FEB/2025	-	-	-	-
046	C. Sanitari de Terrassa	Dr. Blanco	14/MAR/2025	-	-	-	-
016	H. U. Vall d'Hebron	Dr. Martínez	14/MAR/2025	-	-	-	-
035	H. U. Politécnico La Fe	Dr. Juan-Vidal	21/MAR/2025	-	-	-	-
009	H. Clínico San Carlos	Dr. Antoñanzas	28/MAR/2025	-	-	-	-
029	H. U. Basurto	Dr. Sala	28/MAR/2025	-	-	-	-
008	ICO Bellvitge	Dr. Nadal	07/APR/2025	-	-	-	-
023	H. G. U. de Elche	Dr. Benítez	19/MAY/2025	-	-	-	-
036	H. U. La Paz	Dr. De Castro	03/JUN/2025	-	-	-	-
			TOTAL	22	13	0	13

- **Primary objective:** Evaluate the disease-free survival (DFS): defined as the length of time from randomization to the earliest event defined as disease recurrence, any new lung cancer (even in the opposite lung), or death from any cause at any known point in time.

Sponsor: GECP
Planned number of patients: 129 pts.
Patients enrolled: 13 pts.

ARCH

A randomised phase III trial of adjuvant cemiplimab in patients with resected stage II-IIIA NSCLC who have not received prior adjuvant chemotherapy.



Centros participantes

HOSPITAL
HOSPITAL GENERAL UNIV. DR. BALMIS DE ALICANTE
HOSPITAL CLÍNICO SAN CARLOS
HOSPITAL UNIVERSITARIO VALL D'HEBRON
HOSPITAL DE LA SANTA CREU I SANT PAU
COMPLEXO HOSPITALARIO A CORUÑA

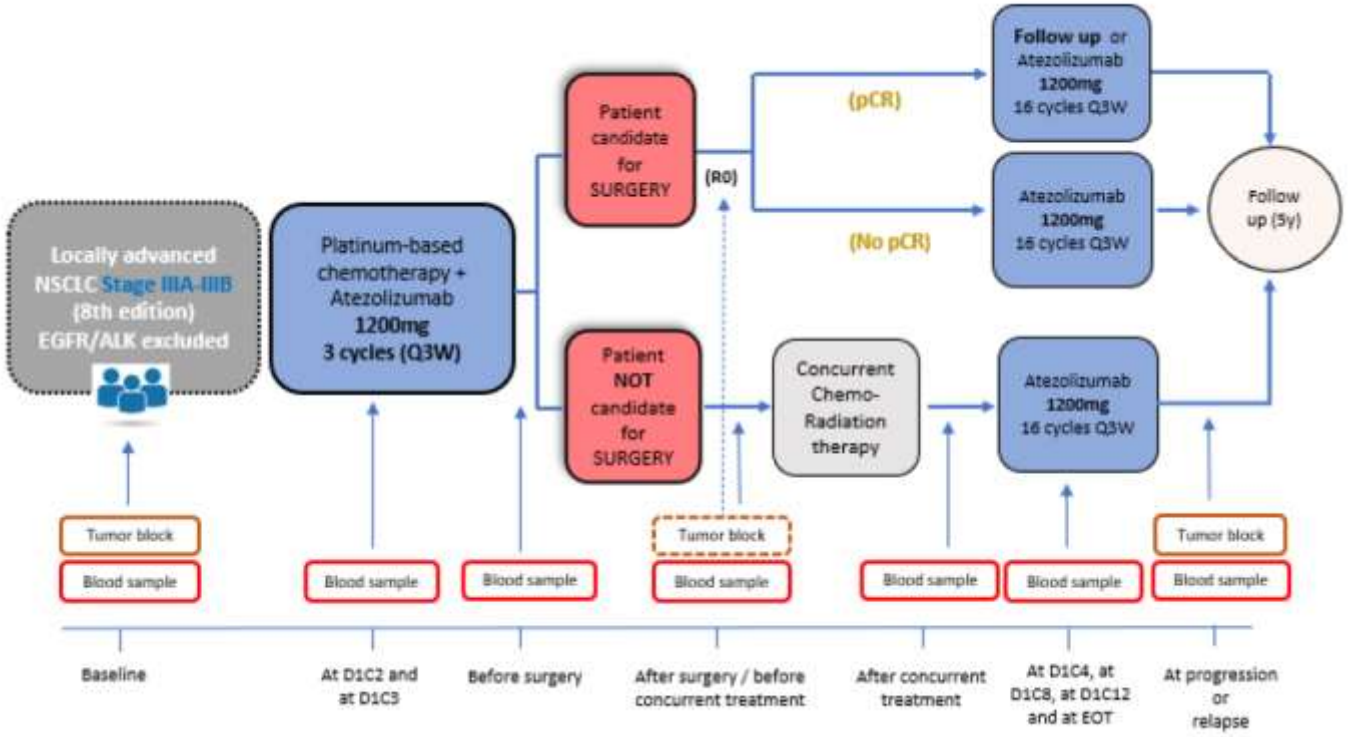
HOSPITAL
HOSPITAL UNIV. NUESTRA SEÑORA DE CANDELARIA
HOSPITAL GENERAL UNIV. VALENCIA
HOSPITAL UNIVERSITARIO CRUCE
HOSPITAL CLÍNICO SAN CECILIO
HOSPITAL UNIV. DE JEREZ DE LA FRONTERA

- **Primary objective:** To determine the efficacy of adjuvant cemiplimab, as measured by disease-free survival (DFS), in patients with resected stage II–IIIA NSCLC and centrally confirmed PD-L1 ≥1% who have not received prior adjuvant platinum-based chemotherapy, compared with observation without adjuvant treatment.

Sponsor: ETOP IBCSG Partners Foundation
Planned number of patients: 390 patients.
International recruitment not yet started.

ATHENEA

Phase II clinical trial of chemotherapy + atezolizumab for stage IIIA and IIIB non-small cell lung cancer followed by atezolizumab as adjuvant treatment after surgery and atezolizumab as maintenance treatment for non-resected patients after chemoradiotherapy.



Nºt	HOSPITAL	IP	FECHA APERTURA	REGISTRADOS	INCLUIDOS
01	H. Dr. Balmis	Dr. Massutí	16/JUL/2025	4	4
15	C. H. U. A Coruña	Dra. García	06/JUN/2025	2	1
21	ICO Girona	Dra. Sais	20/MAY/2025	2	1
03	H. General de Valencia	Dra. Espinosa	24/JUL/2025	1	1
16	H. Vall d'Hebrón	Dr. Martínez	25/AGO/2025	1	1
29	H. Basurto	Dra. Sala	01/JUL/2025	1	1
63	H. Salamanca	Dr. Olivares	25/JUN/2025	1	1
78	H. San Cecilio	Dra. Sequero	19/SEP/2025	1	1
10	H. Sant Pau	Dr. Barba	08/OCT/2025	1	1
02	H. ICO Badalona	Dr. Carcereny	18/JUL/2025	1	0
74	H. Dr. Negrín	Dr. Aguiar	25/AGO/2025	0	0
127	H. Jerez de la Frontera	Dra. Moreno	23/SEP/2025	0	0
72	H. Lucus Augusti	Dra. Campo	30/SEP/2025	0	0
22	H. Son Llàtzer	Dr. Coves	07/OCT/2025	0	0
94	Complejo Hospitalario de Navarra	Dra. Martínez	08/OCT/2025	0	0
55	H. Nª Sra. De la Candelaria	Dra. Medina	SIV - 23/OCT/2025	NA	NA
05	H. Puerta de Hierro	Dr. Provencio	SIV – 24/OCT/2025	NA	NA
53	H. Virgen del Rocío	Dra. Bernabé	SIV – 24/OCT/2025	NA	NA
40	H. Parc Taulí	Dra. Vilà	SIV – 10/NOV/2025	NA	NA
07	Fundación Jiménez Díaz	Dr. Dómine	SIV – 17/NOV/2025	NA	NA
58	H. Sant Joan de Reus	Dra. Lucía	Pendiente contrato	NA	NA
			TOTAL	15	12

- **Primary Objective:** The primary objective is to evaluate the Progression free survival (PFS) rate at 18 months in the intent-to-treat population (ITT).

Sponsor: GECP
Planned number of patients: 97 patients.
Patients enrolled (oct/25): 12 patients.

MERIT-lung

Phase II clinical trial of AMG510 (Sotorasib) in stage III unresectable NSCLC KRAS p.G12C patients.

- **Primary Objective:** To evaluate the efficacy of induction treatment of AMG510 (Sotorasib) plus AMG510 (Sotorasib) treatment post-induction as measured by Progression Free Survival at 12 months (PFS12).

Sponsor: GECP
Planned number of patients: 19 patients
Patients enrolled: 14 patients

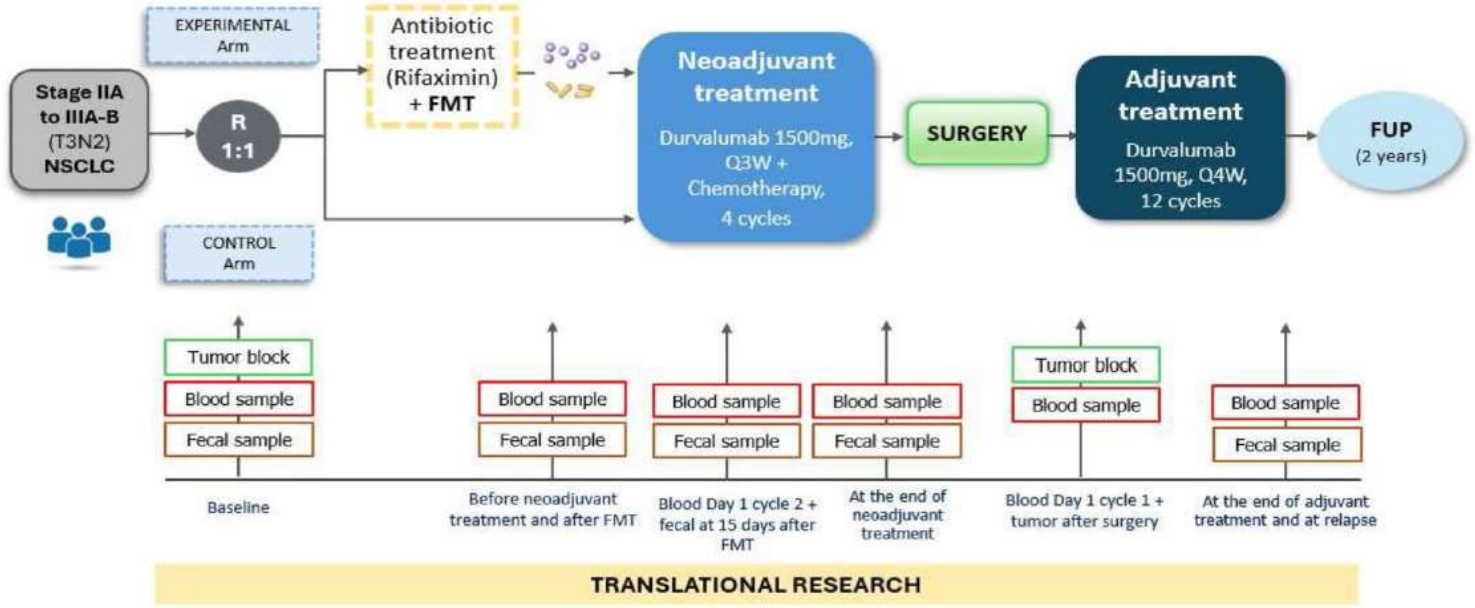
Centros participantes

HOSPITAL	Incluidos
H. Puerta de Hierro	3
H. FJD	3
HU Quirón-Dexeus	2
HC San Cecilio	2
H. Severo Ochoa	1
H. de Basurto	1
HGU Valencia	1
HU Son Espases	1
CS Parc Taulí	-
HU Lucus Augusti	-

HOSPITAL	Incluidos
HGU Alicante	-
CH de Jaén	-
HU Vall d'Hebrón	-
HU Son Llatzer	-
ICO Girona	-
H. Teresa Herrera	-
ICO Badalona-HUGTP	-
HU Virgen del Rocío	-
H. Univ. y Polit. La Fe	-
H. Clínico San Carlos	-

MIGRANT

Phase II randomized clinical trial for evaluating the safety and feasibility of fecal microbiota transplant (FMT) in stage II-III non-small cell lung cancer (NSCLC) patients, using immune checkpoint inhibitors (ICI) responders as donors.



- **Primary Objective:** Assess the pathological complete response (pCR) rate after neoadjuvant treatment

Sponsor: GECP
Planned number of patients: 68 patients.
Recruitment pending start.

Centros participantes

HOSPITAL
ICO HOSPITALET -H. DURAN I REYNALS / H. BELLVITGE
HOSPITAL GENERAL UNIV. DR. BALMIS DE ALICANTE
HOSPITAL UNIVERSITARIO VALL D'HEBRON
HOSPITAL DE LA SANTA CREU I SANT PAU
HOSPITAL UNIVERSITARIO PUERTA DEL HIERRO
ICO BADALONA - HOSPITAL GERMANS TRIAS I PUJOL
HOSPITAL UNIVERSITARIO FUNDACIÓN JIMÉNEZ DÍAZ
HOSPITAL CLÍNICO SAN CARLOS
HOSPITAL UNIVERSITARIO LUCUS AUGUSTI
HOSPITAL UNIVERSITARIO 12 DE OCTUBRE

HOSPITAL
HOSPITAL CLÍNICO UNIVERSITARIO DE VALENCIA
HOSPITAL REGIONAL UNIVERSITARIO DE MÁLAGA
HOSPITAL UNIVERSITARIO Y POLITÉCNICO LA FE
HOSPITAL UNIV. NUESTRA SEÑORA DE CANDELARIA
HOSPITAL GENERAL UNIVERSITARIO DE ELCHE
COMPLEJO HOSPITALARIO UNIVERSITARIO DE VIGO
HOSPITAL CLÍNICO UNIVERSITARIO DE SANTIAGO
HOSPITAL UNIVERSITARI DEXEUS
HOSPITAL GENERAL UNIVERSITARIO MORALES MESEGUER
HOSPITAL SAN CECILIO

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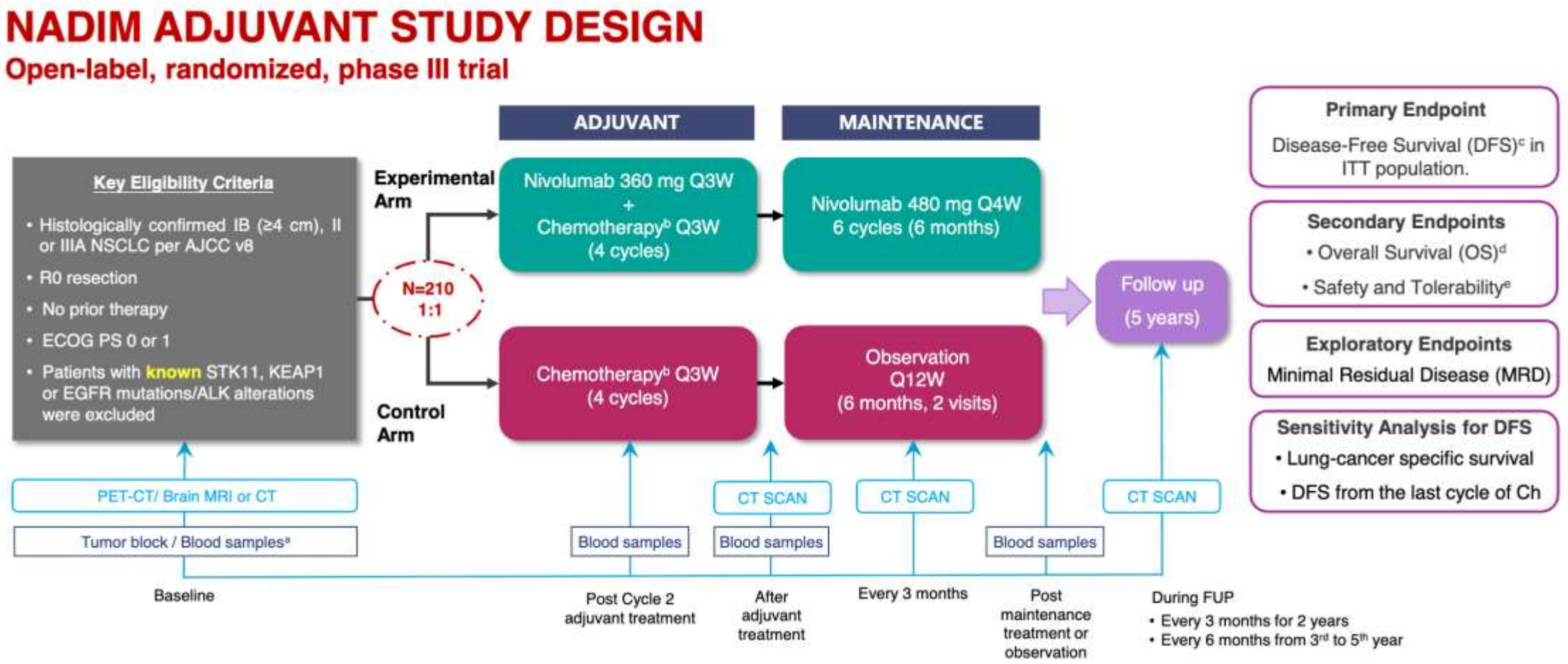
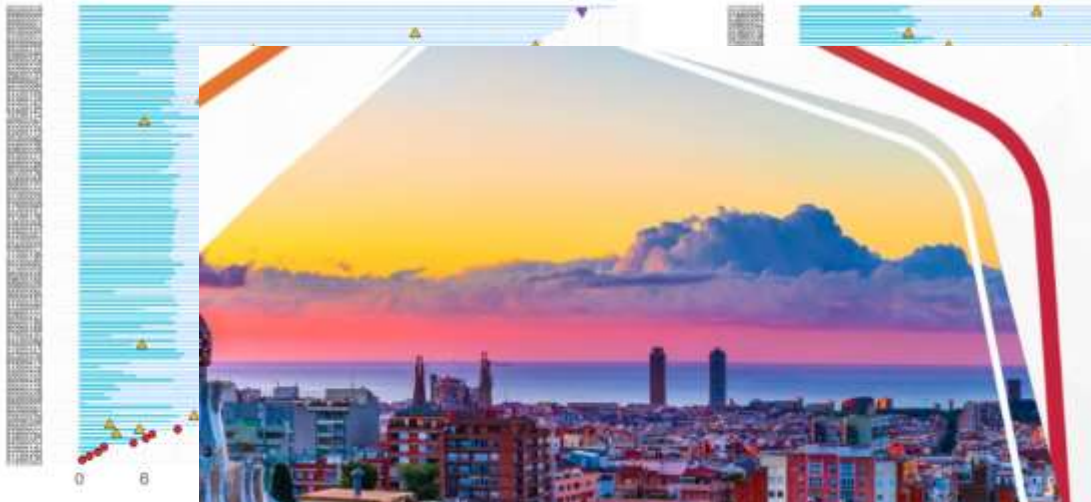
NADIM-Adjuvant

A Phase III Clinical Trial of Adjuvant Chemotherapy vs Chemoimmunotherapy for Stage IB-IIIA Completely Resected Non-small Cell Lung Cancer (NSCLC) Patients.



SWIMMER PLOT: EXPERIMENTAL GROUP

SWIMMER PLOT: CONTROL GROUP



A total of 61 eve

IASLC 2025 World Conference on Lung Cancer

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wclc.iaslc.org #WCLC25

NADIM ADJUVANT trial

A phase III clinical trial of adjuvant chemotherapy vs chemo-immunotherapy for stage IB-IIIA completely resected non-small cell lung cancer (NSCLC) patients

First Interim Analysis

M. Provencio, R. Bernabé, E. Nadal, A. Martínez-Marti, E. Carcereny, A. Ortega, B. Campos, M. Dómine, B. Massuti, M. Martínez Aguillo, I. Sullivan, A. Padilla, J. González-Larriba, R. García Campelo, J. Bosch-Barrera, S. Sandiego, O. Juan-Vidal, D.Rodriguez, A. Blasco, L. Vilà, P. Martín-Martorell, R. Marsé, X. Mielgo, J. de Castro, J. Mane, J. Aires Machado, M. Sala, M. Lázaro-Quintela, R. Palmero, V. Calvo, on behalf of Spanish Lung Cancer Group.

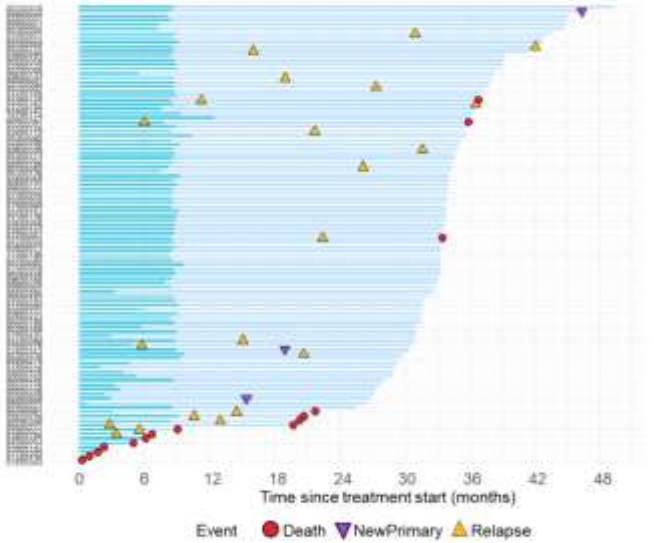
CONQUERING LUNG AND OTHER THORACIC CANCERS WORLDWIDE IN THE 21ST CENTURY

	Experimental (n=103)	Control (n=103)
	0.54 (0.32-0.93)	
	0.025	

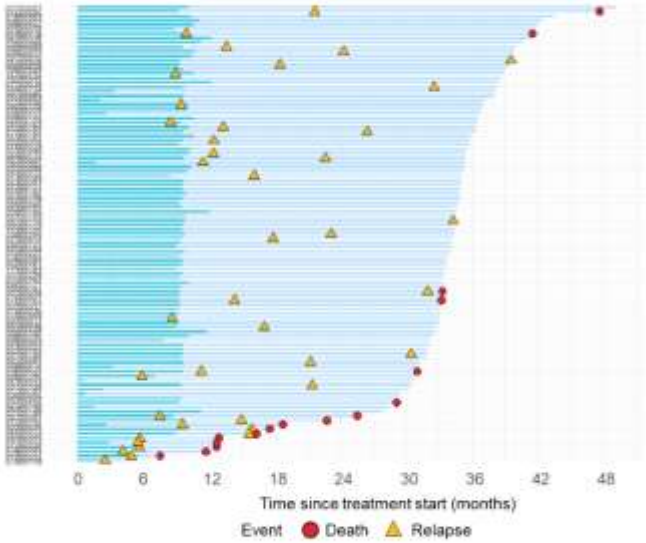
ty data: 57%

Number at risk (events)													
Experimental group	103	(4)	94	(3)	90	(5)	85	(5)	80	(2)	67	(2)	21
Control group	103	(6)	96	(9)	87	(11)	76	(6)	70	(2)	63	(3)	18

SWIMMER PLOT: EXPERIMENTAL GROUP



SWIMMER PLOT: CONTROL GROUP



A total of 61 events were reported, with 21 (20.4%) occurring in the experimental group and 40 (38.8%) in the control group.

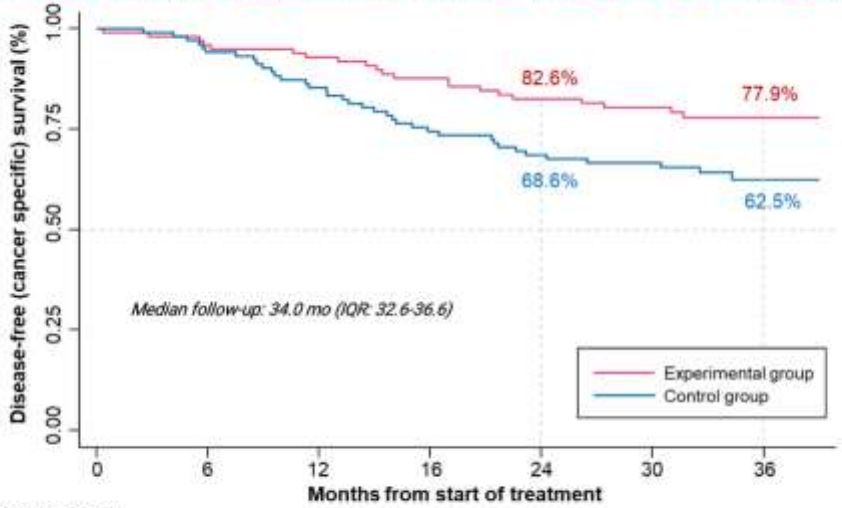
61 events were reported

20,4% experimental arm vs. 38,8% in control arm.

DFS cancer-specific

24months: 82,6% vs. 68,6%
HR 0,54 (0,32-0,93); p=0.025

NADIM ADJUVANT: SENSITIVITY ANALYSIS, DFS CANCER-SPECIFIC



	Experimental (n=103)	Control (n=103)
HR_{3years} (95% CI)	0.54 (0.32-0.93)	
P value	0.025	

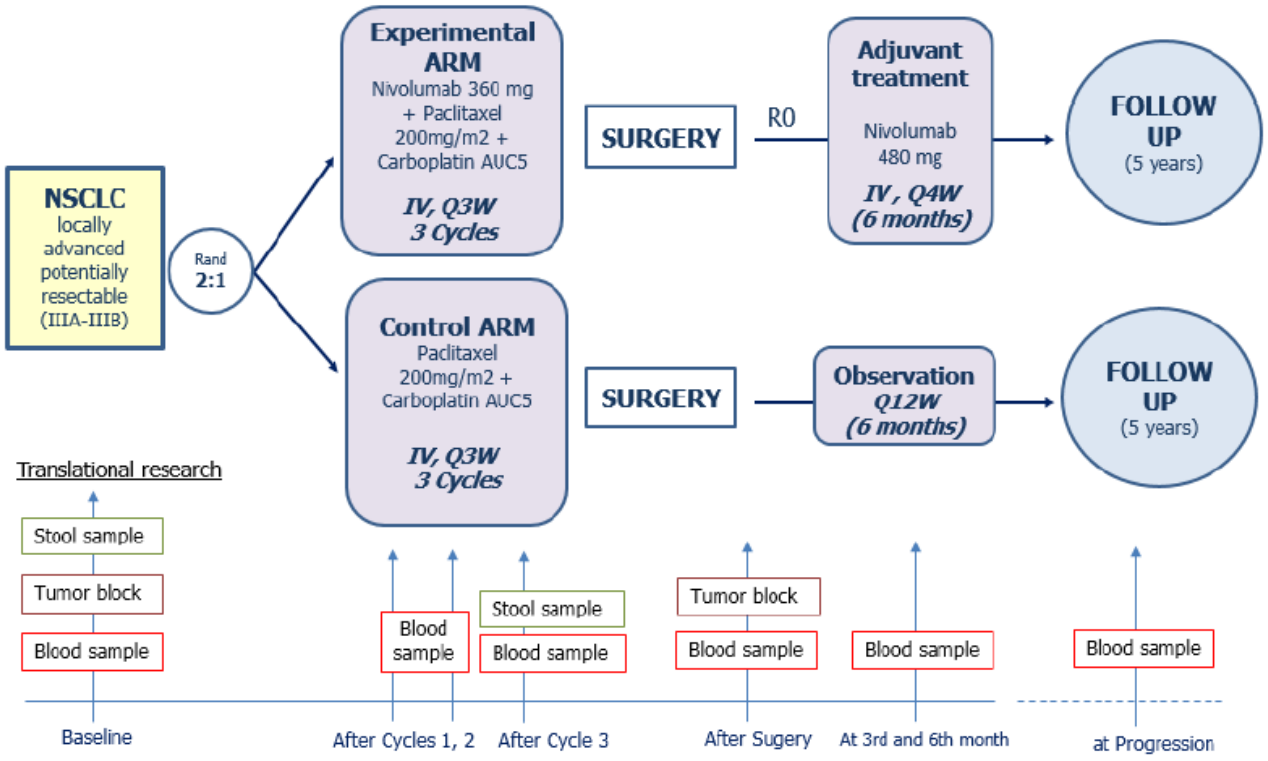
Maturity data: 57%

Number at risk (events)

Experimental group	103	(4)	94	(3)	90	(5)	85	(5)	80	(2)	67	(2)	21
Control group	103	(6)	96	(9)	87	(11)	76	(6)	70	(2)	63	(3)	18

NADIM II

A randomized phase II study of neo-adjuvant chemo/immunotherapy versus chemotherapy alone for the treatment of locally advanced and potentially resectable non-small cell lung cancer (NSCLC) patients.



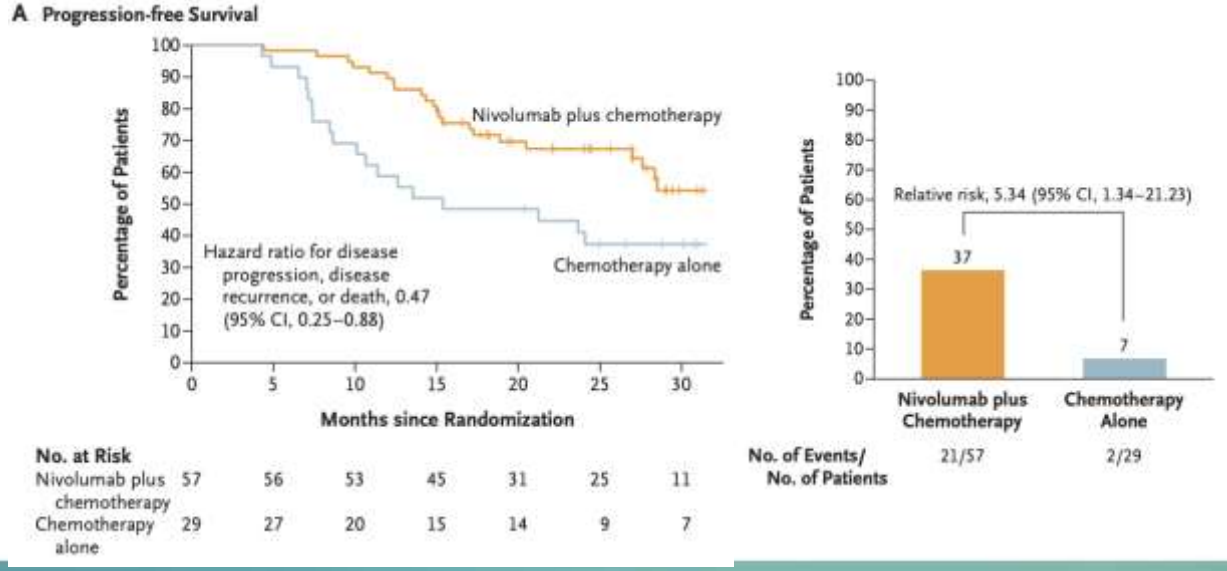
Nº pacientes previstos: 90
Pacientes randomizados: 90 (Inclusión cerrada)
Pacientes válidos: 88

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Perioperative Nivolumab and Chemotherapy in Stage III Non–Small-Cell Lung Cancer

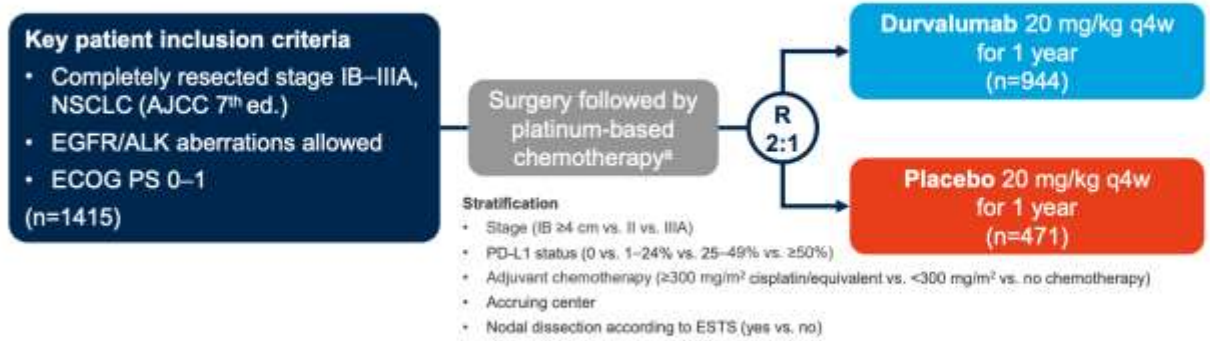
M. Provencio, E. Nadal, J.L. González-Larriba, A. Martínez-Martí, R. Bernabé, J. Bosch-Barrera, J. Casal-Rubio, V. Calvo, A. Insa, S. Ponce, N. Reguart, J. de Castro, J. Mosquera, M. Cobo, A. Aguilar, G. López Vivanco, C. Camps, R. López-Castro, T. Morán, I. Barneto, D. Rodríguez-Abreu, R. Serna-Blasco, R. Benítez, C. Aguado de la Rosa, R. Palmero, F. Hernando-Trancho, J. Martín-López, A. Cruz-Bermúdez, B. Massuti, and A. Romero



LINC (BR.31)

A Phase III prospective double blind placebo controlled randomized study of adjuvant MEDI4736 in completely resected NSCLC.

- **Study objective**
  - To evaluate the efficacy and safety of adjuvant durvalumab in patients with completely resected NSCLC in the phase 3 CCTG BR.31 study

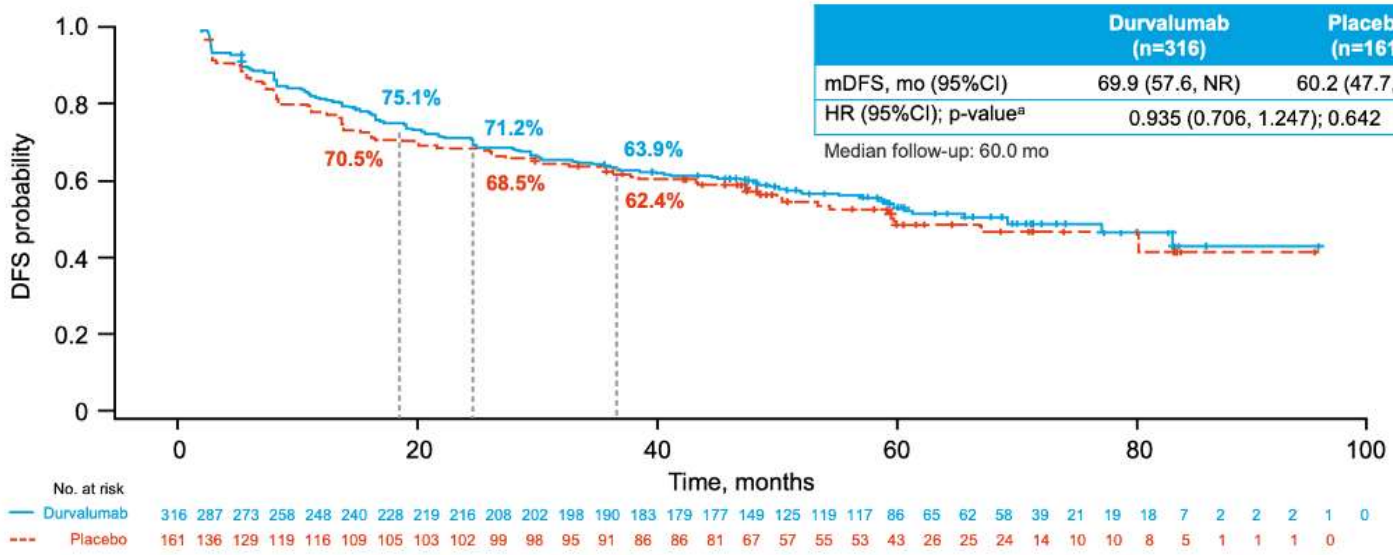


Primary endpoint
- DFS in PD-L1 TC ≥25% EGFR-/ALK- (investigator assessed)

Secondary endpoints
- DFS, OS, QoL, safety

Conclusions: In patients with completely resected NSCLC, adjuvant durvalumab failed to show improvement in DFS outcomes, regardless of the PD-L1 tumor score, and had a safety profile consistent with previous findings

DFS in PD-L1 TC ≥25% EGFR-/ALK-



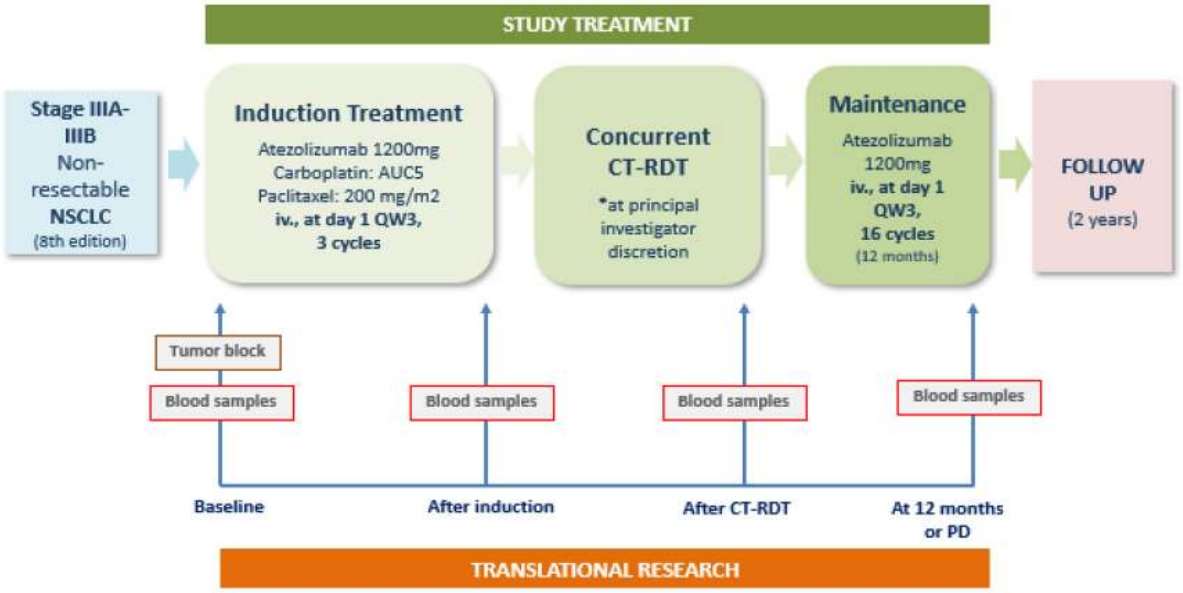
	Durvalumab (n=316)	Placebo (n=161)
mDFS, mo (95%CI)	69.9 (57.6, NR)	60.2 (47.7, NR)
HR (95%CI); p-value[a]	0.935 (0.706, 1.247); 0.642	

Median follow-up: 60.0 mo

SPONSOR: CCTG.
Spanish sponsor: GECP.
Patients randomised in Spain: 119 patients
Data presented at ESMO 2024

APOLO

A phase II trial of Atezolizumab plus induction chemotherapy (CT) plus chemoradiotherapy and Atezolizumab maintenance therapy in non-resectable stage IIIA-IIIB-IIIC non-small cell lung cancer (NSCLC) patients.



Nº pacientes previstos: 37 pacientes

Pacientes incluidos: 38 pacientes (32 pacientes elegibles).

Conclusions: Our study provides better results than those historically known (PACIFIC trial) and encourages the development of strategies like those already successfully used in earlier stages.

- **Primary objective:** To assess the efficacy of the treatment (atezolizumab + induction chemotherapy + chemo-radiotherapy) in terms of progression-free survival (PFS) at 12 months.
- **Results:**
  - ✓ 100% pts started concurrent CT/RT.
  - ✓ **12-months PFS (ITT): 68,4%**
  - ✓ 12-months OS (ITT): 86,8%
  - ✓ **Toxicity grade 3-4 AEs:**
    - ➢ Induction: 23,7%
    - ➢ **Concurrent CT/RT: 34,2%**
    - ➢ Maintenance phase: 13,2%

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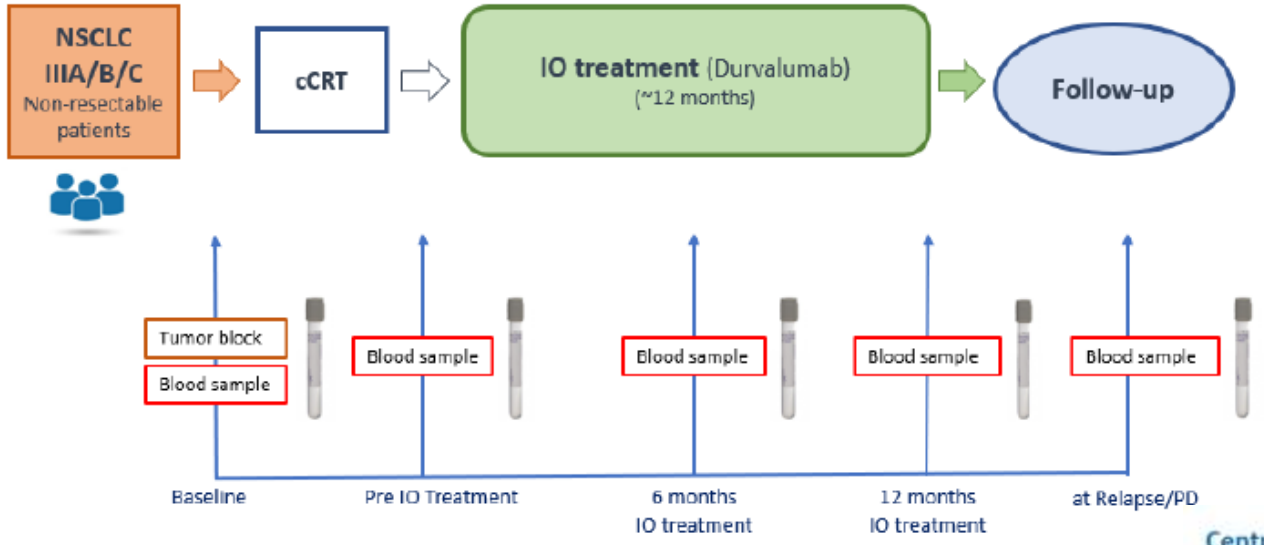
SIENNA

Study of antitumor immune response generated after concurrent chemo-radiotherapy (cCRT) and IO treatment in non-resectable stage IIIA/B and IIIC NSCLC patients treated in real world.



Sponsor: GECP
Planned number of patients: 75 patients
Number of patients included: 60 patients.

- **Primary objective:** To evaluate overall survival (OS) and progression-free survival (PFS) in unresectable stage III NSCLC patients treated with concurrent chemoradiotherapy followed by durvalumab in real-world clinical practice, and to explore the association between antitumor immune response — including circulating tumour DNA (ctDNA) dynamics — and clinical outcomes

Centros participantes

HOSPITAL	Incluidos
ICO GIRONA	10
H. U. CENTRAL ASTURIAS	10
H.U. NTRA SRA CANDELARIA	6
H. U. DE GC DR. NEGRÍN	5
H. SANT PAU	4
H. LA PAZ	4
H. BASURTO	3
H. VALL HEBRÓN	3
H. U. DR. BALMIS ALICANTE	2
H. PUERTA HIERRO	2
H. U. DE LA PRINCESA	2

HOSPITAL	Incluidos
H. G. TRIAS I PUJOL	2
C.H.U. VIGO	1
H. CLÍNICO SAN CARLOS	1
H. C. U. VALLADOLID	1
FUNDACIÓN JIMÉNEZ DÍAZ	1
H. U. DEL FERROL	1
H. U. A CORUÑA	1
H. G. U. CIUDAD REAL	1
H. LUCUS AUGUSTI	0
H. LA FE	0
H. VIRGEN DEL ROCÍO	0

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- Active studies in recruitment or planned to start
- Active studies with recruitment closed
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SCIENTIFIC ACTIVITY IN 2025

PUBLISHED PAPERS

- Peripheral memory B cell population maintenance and long-term survival after perioperative chemoimmunotherapy in NSCLC (NADIM trial). ONCOIMMUNOLOGY 2025, VOL. 14, NO. 1, 2513109. https://doi.org/10.1080/2162402X.2025.2513109.

CONFERENCE PRESENTATIONS

- **ELCC 2025 (Poster presentation):** Prognostic Value of Minimal Residual Disease in the NADIM II Trial.
- **AACR 2025 (Poster):** B cells mediate antitumor immune response and predict pathological response in locally advanced NSCLC patients treated with perioperative chemoimmunotherapy (NADIM trials).
- **IASLC 2025 (Poster):** ARIAN, Adjuvant tReatment with sacItuzumab and ZimberelimAb in resected pa-tieNts: a phase III study – Trial in Progress.
- **IASLC 2025 (Presidential Symposium):** Adjuvant chemotherapy (CT) vs CT-immunotherapy for R0 stage IB-IIIA NSCLC patients (NADIM ADJUVANT): a randomised, phase 3 trial.
- **IASLC 2025 (Mini-Oral):** Metabolomic Analysis Identifies Histamine as a Key predictive factor for Perioperative Chemoimmunotherapy in NADIM II Trial.
- **IASLC 2025 (Mini-Oral):** Surgical outcomes and oncological quality of surgery according to IASLC criteria in NADIM II trial.
- **IASLC 2025 (Mini-Oral):** Pharmacoeconomic analysis of NADIM 2 Trial: cost-e!ectiveness of perioperative chemo immunotherapy in resectable Stage III NSCLC.
- **ESMO 2025 (Poster):** Cost-effectiveness analysis of perioperative chemoimmunotherapy in Stage III Non Small Cell Lung Cancer. Analysis of role of postoperative Nivolumab.
- **SEOM 2025: Plenary +** Oral + Poster.

CONCLUSIONS

- GECP is conducting an ongoing, comprehensive research programme in localised NSCLC, ranging from **adjuvant strategies (ARCH), perioperative (NADIM, ARIAN and ATHENEA), to unresecatable locally advanced stages (APOLO).**

- NADIM and NADIM II trials continue to deepen our **understanding of neoadjuvant chemo-immunotherapy through ongoing translational studies.**

- **NADIM ADJUVANT trial is evaluating adjuvant combined CT-IO as a potential future standard of care with promising results.**

16th CONGRESS Lung ON CANCER

BARCELONA
27 / 28
NOVEMBER 2025

THANK YOU

GECP
lung cancer research