V Reunión Anual de Cáncer

Investigación en Tumores Hepato-Bilio-Pancreáticos, neuroendocrinos y otros tumores digestivos

16 Junio 2023

Equipo de Oncología Digestiva FJD
Servicio de Oncología Médica / Oncohealth Institute
Hospital Universitario Fundación Jimémez Díaz

Dr Angela Lamarca MD, PhD, MSc
Dr Eva Ruiz MD
Dr Raquel Fuentes MD

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Grupo quirónsalud

¿Quiénes somos?

- Medical Oncolgoist:
  - Dr Angela Lamarca MD, PhD, MSc
  - Dr Eva Ruiz MD
  - Dr Raquel Fuentes MD

- Research team
  - Berta Martín: study coordinator
  - Leticia Sanchez: data entry
  - Research nurses: Sergio Galán / Paula Gomez

¿Quiénes somos?

- Medical Oncolgoist:
  - **Dr Angela Lamarca MD, PhD, MSc (2022)**
  - Dr Eva Ruiz MD
  - **Dr Raquel Fuentes MD (2023)**

- Research team
  - Berta Martín: study coordinator
  - **Leticia Sanchez: data entry (2023)**
  - Research nurses: Sergio Galán / **Paula Gomez (2023)**

Un grupo en proceso de CREACIÓN pero con gente con MUCHA EXPERIENCIA y muchas GANAS!

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My Madrid-Manchester-Madrid Journey: 2013-2022

- Completed training 2012
  - Medical Oncologist HU Alcala de Henares (Madrid): May 2012-Dec 2012

- ESMO Translational Fellowship 2013-2015
  - Joined The Christie (HPB/NET team) January 2013
  - 2nd year **ESMO Translational Fellowship** prolongation
- Prolongation of Fellowship by other funding sources (2015-2017)
  - **SEOM Fellowship Programme**
  - **ASCO Conquer Cancer Foundation Young Investigator Award**
  - **Cholangiocarcinoma Foundation Fellowship Programme**
- 2017: Locum Consultant in Medical Oncology at The Christie (HPB/NET team)
  - 2018: Consultant in Medical Oncology at The Christie (HPB/NET team): 50% protected time for research
  - **The Christie Charity**

- 2022: Back to Madrid (HU-FJD)
  - **SEOM Beca de Retorno**

My current roles: 2023

Educational activities

Member of ESMO Council 2023

Chair of the ESMO Press and Media Affairs Working Group 2023

Faculty for upper GI malignancies; scientific committee for ESMO 2022, 2023, 2024, ESMO Asia 2023

Member of the ENETS Advisory Board (reelected 2023)

Guideline development:

Member of the ESMO Guidelines Committee – Subject Editor for Endocrine & NET

Authorship group for the ESMO Clinical Practice Guideline on Pancre

Authorship group for the ESMO Clinical Practice Guideline on R

Member of the ESMO/ESTRO "TKI IO vs RT" Project working g

Member of the EASL Guidelines for the Diagnosis and Managem

Reviewer of SEOM-GEMCAD-TTD guidelines in Hepatocelullar carcino

Lead autor for the ENETS small intestinal neuroendocrine guidelines 2023

¡El equipo de oncologia digestiva esta dipueso a colaborar CON TODOS y a ser un ALIADO!

Research roles

Chair of the EORTC GITCG hepatobiliary and neuroendocrine tumours task force (since February 2022 onwards)

Member of the ENS-CCA Steering Committee

Member of International Biliary Tract Cancer Collaborators (IBTCC) since June 2017 onwards

Member of the “Evaluación de Resultados y Práctica Clínica” Section SEOM (February 2022 onwards; expected until 2024)

Member of the “Grupo de Trabajo conjunto con la Red Española de Registros de Cáncer (REDECAN)-SEOM” (February 2022 onwards; expected until 2024)

Member of the TTD Hepato-Biliary working group (June 2022 onwards)

Member of the Ethics Committee for Fundacion Jimenez Diaz University Hospital Research Institute (since September 2022 onwards)

ENS-CCA NETWORK MEMBERS

AUSTRIA

Medical University of Vienna (Vienna)

BELGIUM

Jules Bordet Cancer Institute (Brussels)

DENMARK

University of Copenhagen (Copenhagen)

FRANCE

Saint-Antoine Centre (Paris)
Inserm NuMeCan (Rennes)
Lyonnais Center for Digestive Surgery (Lyon)

GERMANY

University Hospital of Würzburg (Würzburg)
Institute of Pathology (Greifswald)
Saarland University Medical Center (Homburg)
Institute of Pathology - Heidelberg University Hospital (Heidelberg)
Heidelberg University (Heidelberg)
Institute for Pathology - University of Regensburg (Regensburg)
Essen University Hospital (Essen)
RWTH Aachen University (Aachen)
Hannover Medical School (Hannover)
University Medical Centre Hamburg-Eppendorf (Hamburg)
University Hospital Bonn (Bonn)
University Hospital Schleswig-Holstein (Lübeck)

ITALY

Sapienza University of Rome (Rome)
National Cancer Institute Regina Elena (Rome)
Università Politecnica delle Marche - Ospedali Riuniti Univeristy Hospital (Ancona)
University of Milano-Bicocca (Milano)
Humanitas Research Hospital (Milano)
University of Milano (Milano)
University of Florence (Florence)
University of Padua (Padua)
University of Sassari (Sassari)
University of Bologna (Bologna)
National Institute of Gastroenterology "S. De Bellis" Research Hospital (Castellana Grotte)

THE NETHERLANDS

University of Maastrich (Maastrich)/University of Aachen (Aachen)
Erasmus MC Hospital (Rotterdam)
Academic Medical Center (Amsterdam)
Radboud University Nijmegen Medical Centre (Nijmegen)

LITHUANIA

Lithuanian University of Health Science (Kaunas)

NORWAY

Norwegian PSC Research Center (Oslo)
Norwegian Radium Hospital (Oslo)

POLAND

University of Warsaw (Warsaw)
Teaching Hospital No 1 (Rzeszow)

PORTUGAL

University of Lisbon (Lisbon)

SPAIN

Biodonostia Health Research Institute - Donostia University Hospital (San Sebastian)
University of Salamanca - HEVEPHARM (Salamanca)
Centre for Applied Medical Research (CIMA) - Clinica Universidad de Navarra (Pamplona)
"12 de Octubre" University Hospital (Madrid)
Hospital Universitario Fundación Jiménez Díaz (Madrid)
August Pi i Sunyer Biomedical Research Institute - Clinic Universitary Hospital (Barcelona)
Biocruces Bizkaia Health Research Institute (Barakaldo)
Ability Pharma

SWEDEN

Karolinska Institutet (Karolinska)
Sahlgrenska University Hospital (Goteborg)

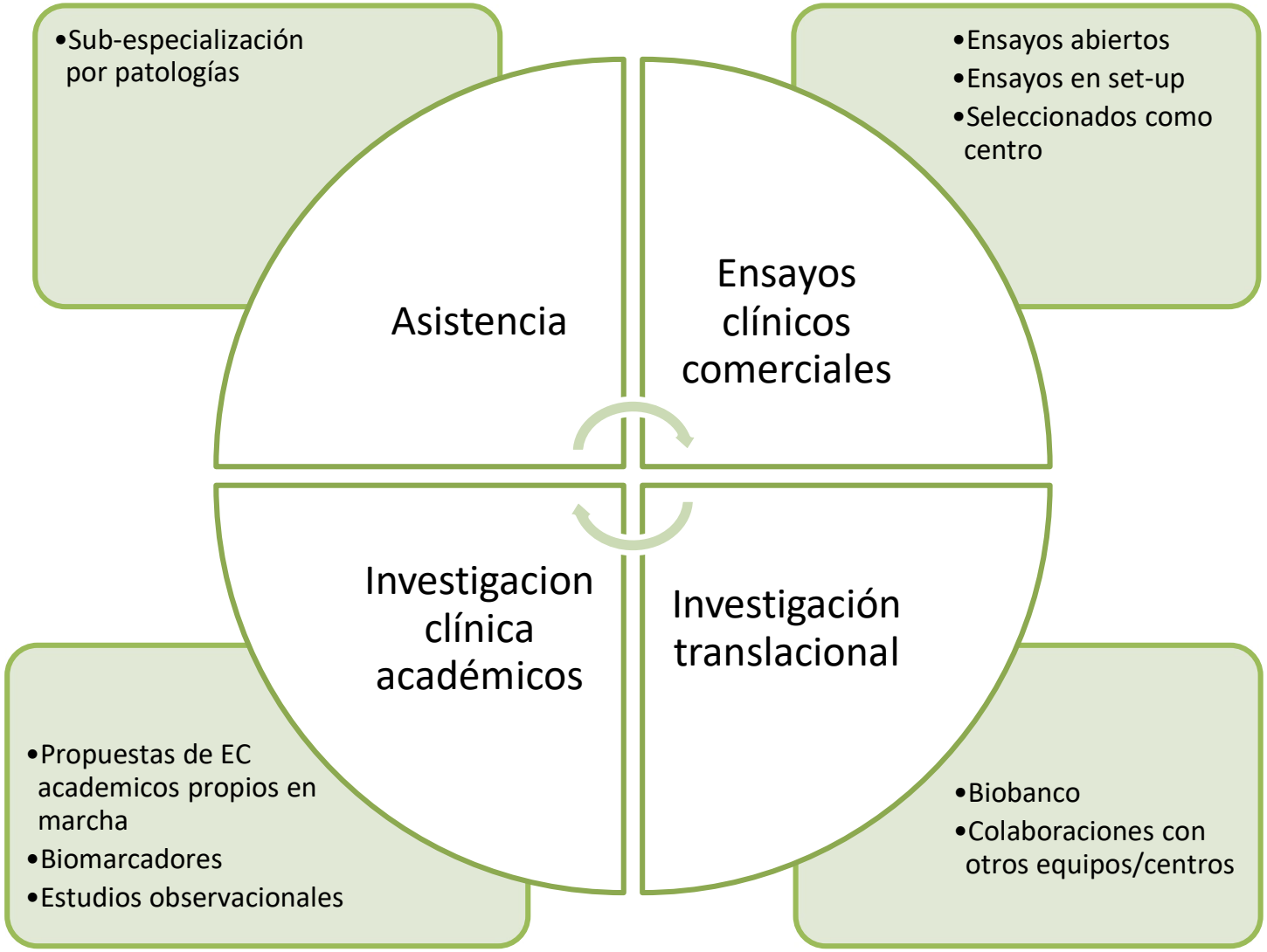
SWITZERLAND

Zurich University Hospital (Zurich)

UNITED KINGDOM

University of Edinburgh (Edinburgh)
University of Glasgow - Beatson West of Scotland Cancer Centre (Glasgow)
University College London Hospital (London)
The Christie NHS Foundation Trust (Manchester)
Imperial College Healthcare NHS Trust - Imperial College London (London)
Queen´s Medical Centre - University of Nottingham (Nottingham)
University of Liverpool (Liverpool)

¿Qué hacemos y hacia dónde vamos?



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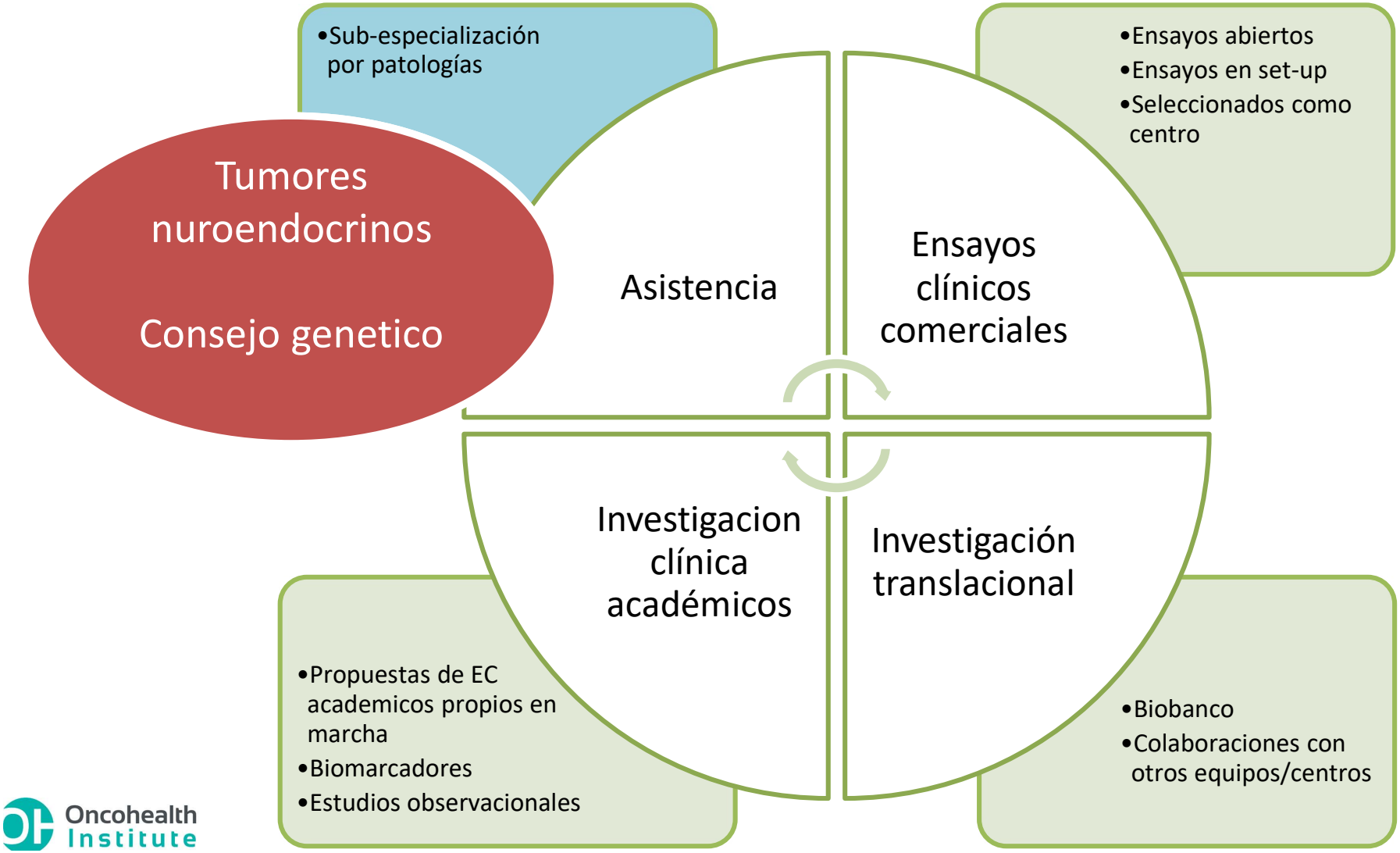

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Spanish CCA Patient association - Work in progress

AMMF
THE CHOLANGIOCARCINOMA CHARITY

Cholangiocarcinoma
Foundation of Thailand

THE cholangiocarcinoma FOUNDATION

APiC
ASSOCIAZIONE PAZIENTI ITALIANI COLANGIOCARCINOMA

Japan
Cholangiocarcinoma
Association
Daisy Association

Spain

Expected first steps Oct 2023

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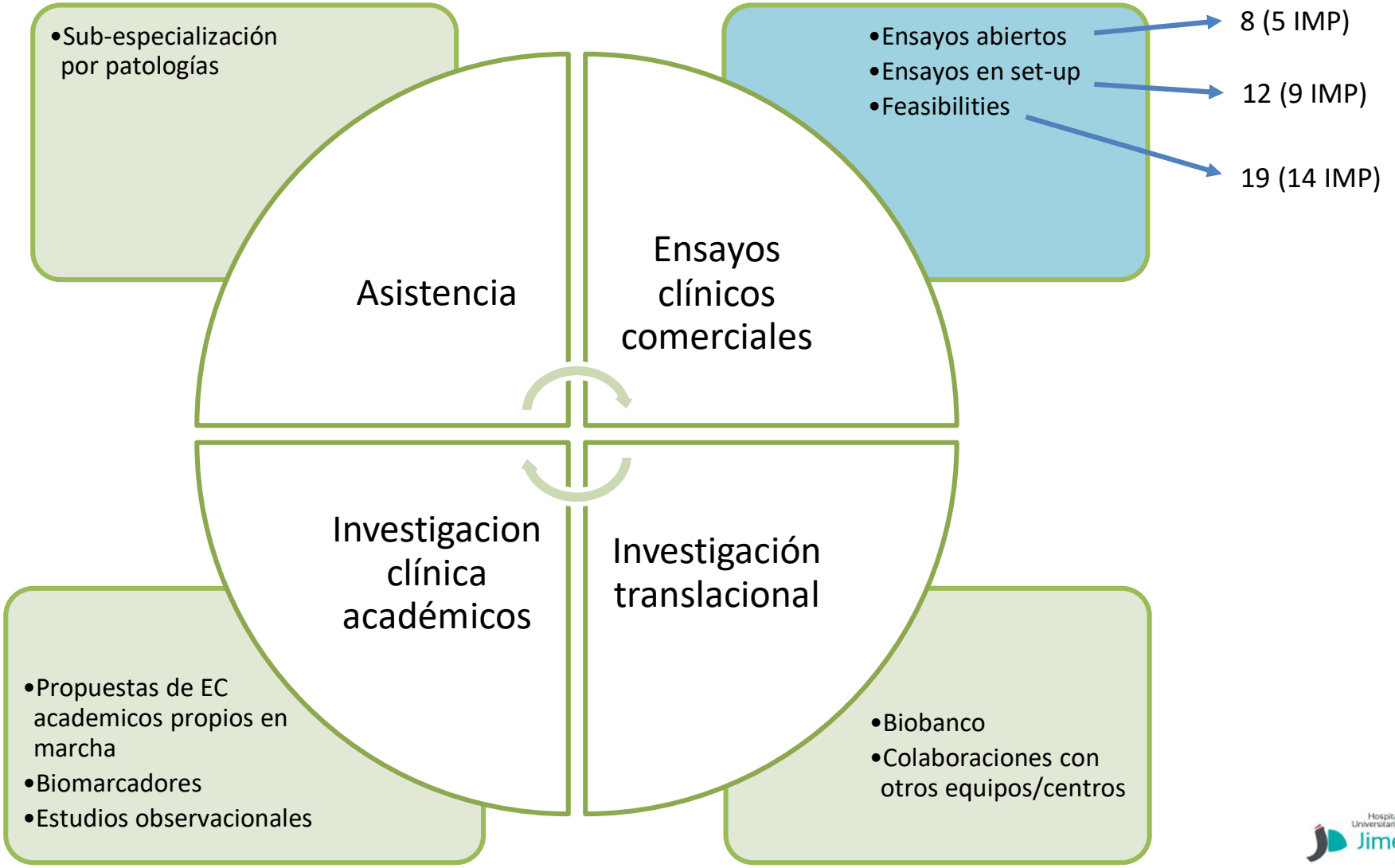

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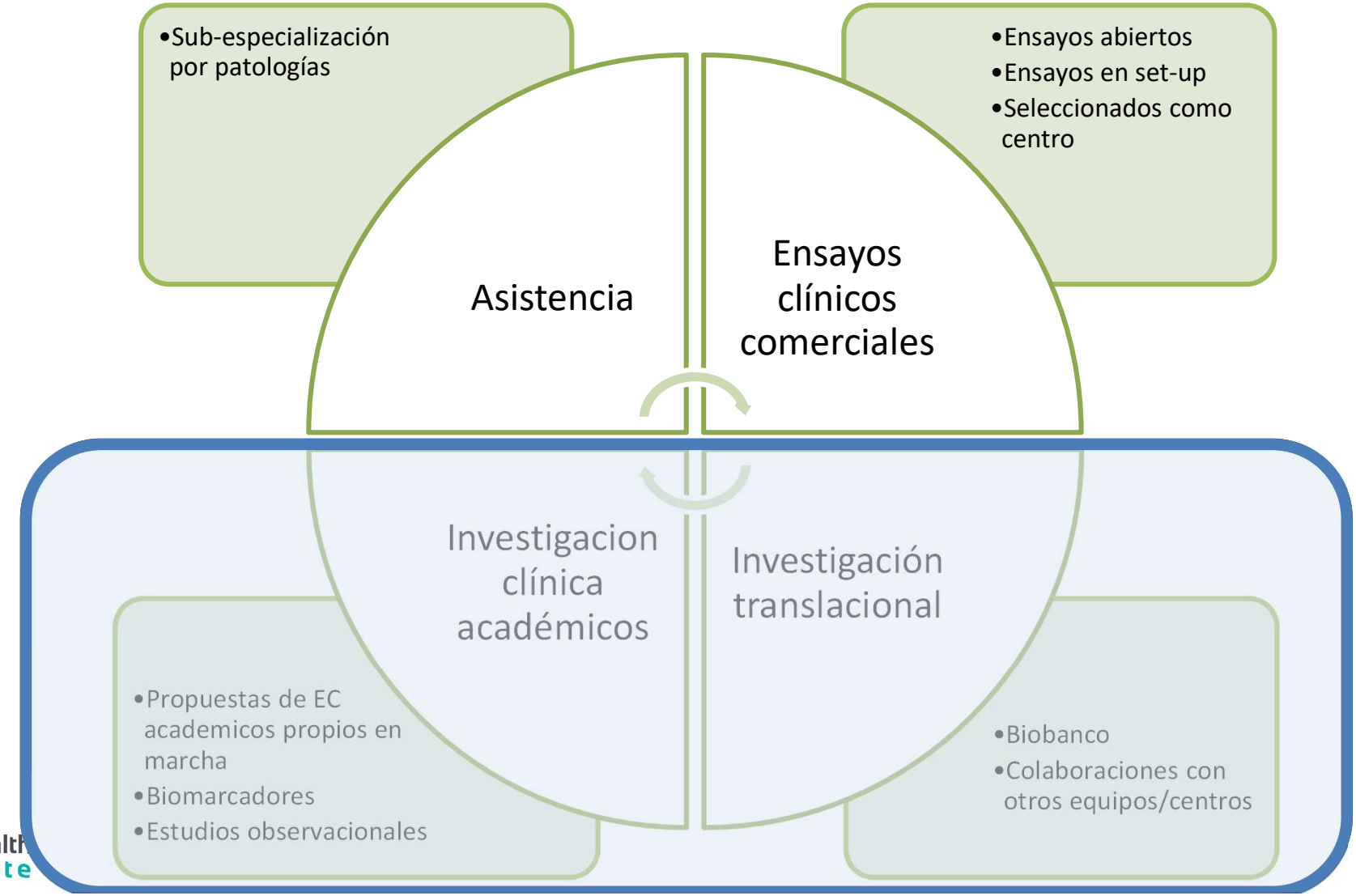

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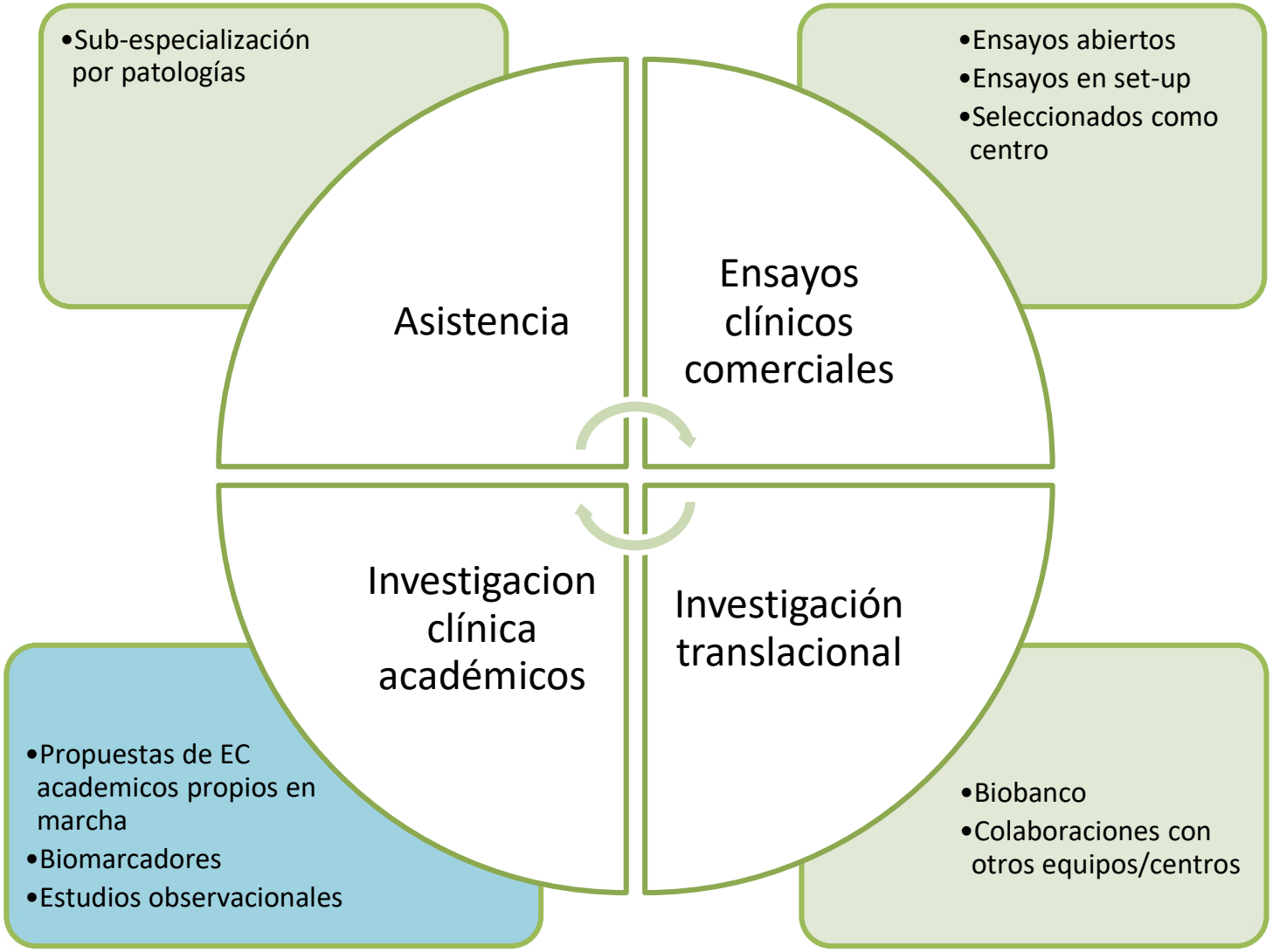

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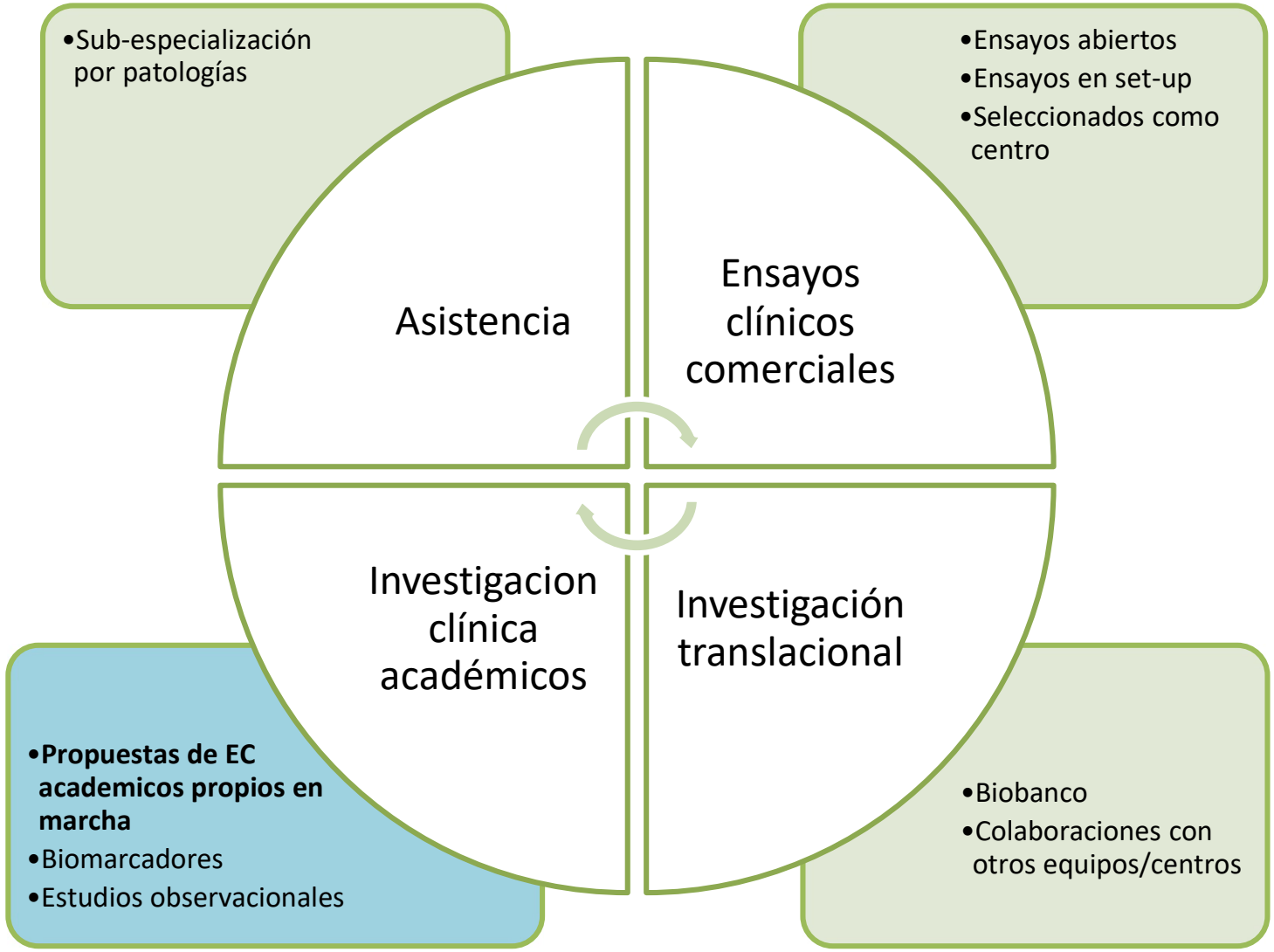
¿Qué hacemos y hacia dónde vamos?



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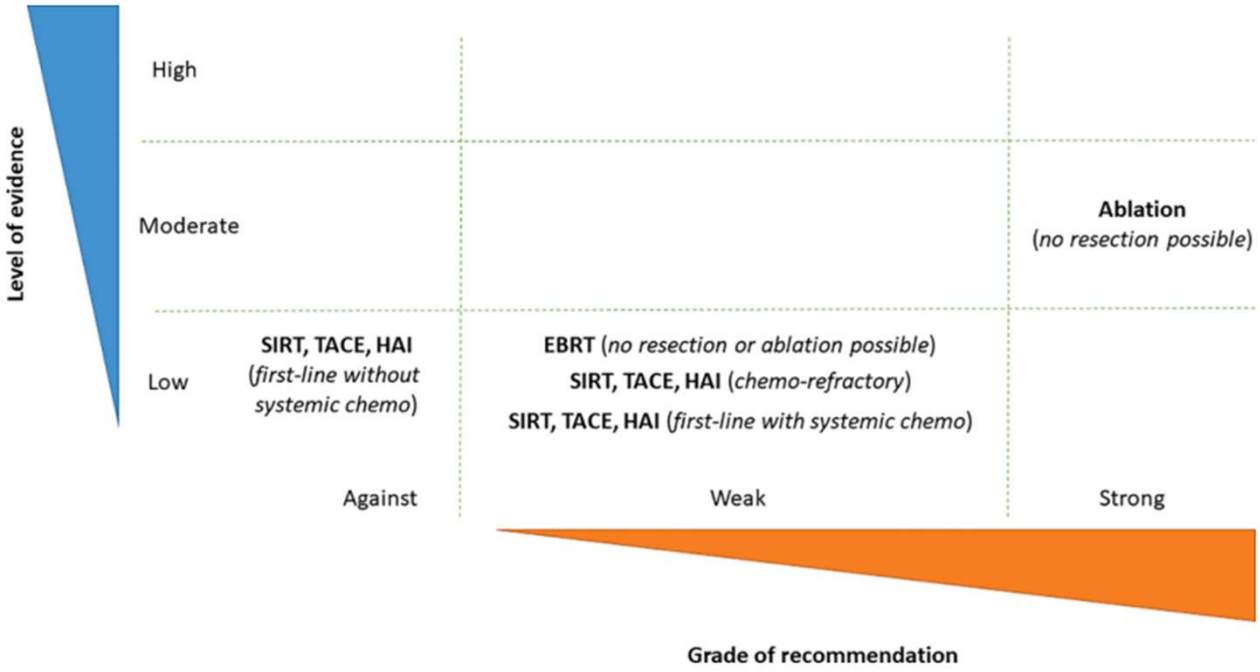
Locoregional therapies in iCCA

- Systematic review and meta-analysis
- 93 studies were eligible: 74% retrospective, 99% non-randomised.
- Pooled mean weighted OS (months):
  - Ablation: 30.2 (95%CI 21.8-38.6)
  - EBRT: 18.9 (95%CI 14.2-23.5)
  - SIRT: 14.1 (95%CI 12.1-16.0)
  - TACE: 15.9 (95%CI 12.9-19.0)
  - HAE 21.3 (95%CI 15.4-27.1)
- Conclusions: Available literature was heterogeneous and of insufficient quality to make strong recommendations. Ablation achieved satisfactory outcomes, and may be recommended when surgery is not feasible.

Proposed recommendations for the current role of loco-regional treatment in the treatment of patients with intrahepatic cholangiocarcinoma

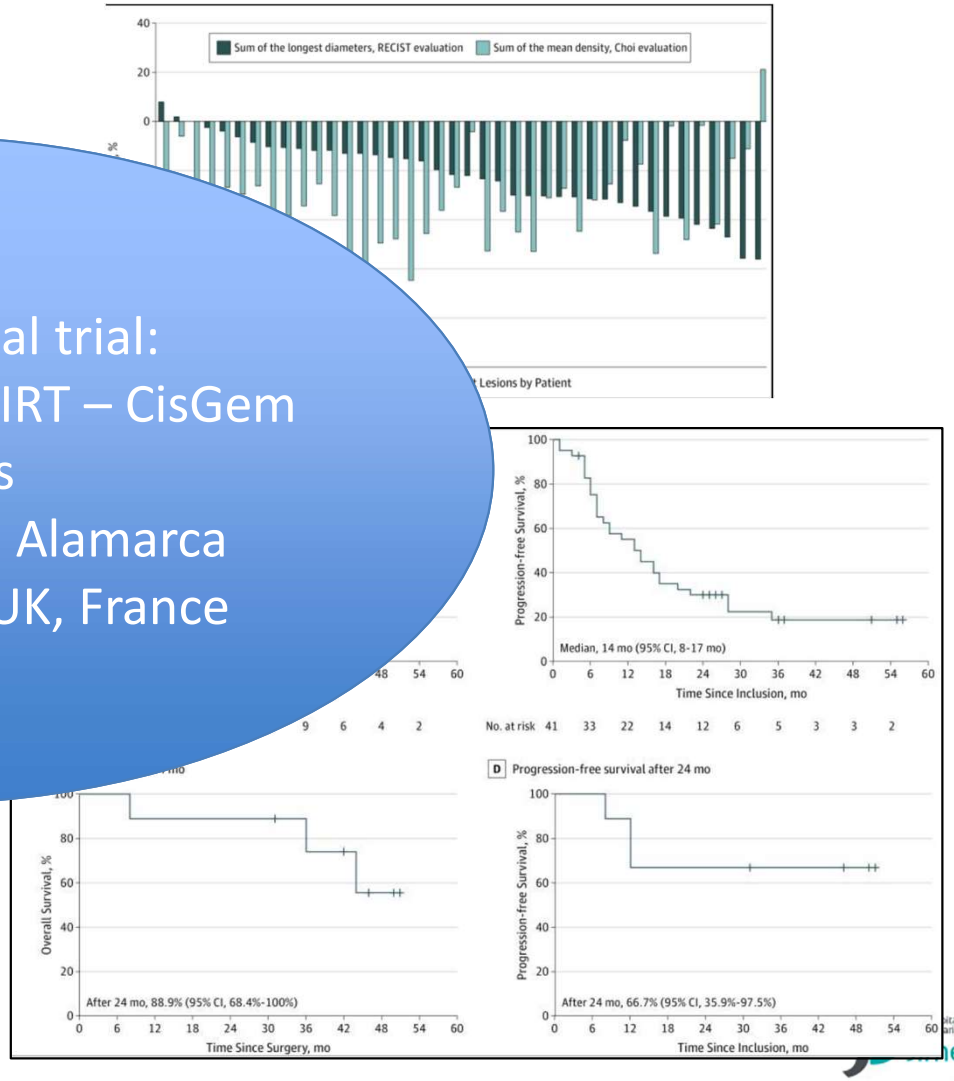


Edeline et al, Cancer Treatment Reviews 2021

Liver Radioembolisation for iCCA

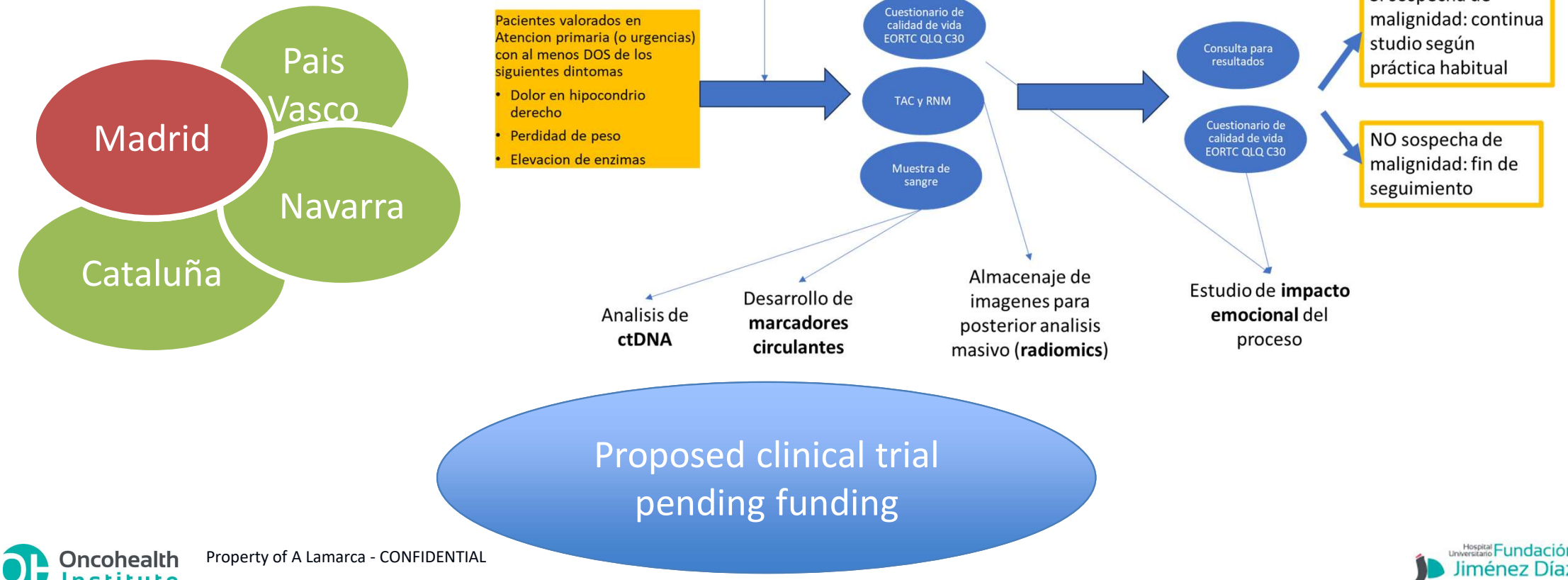
- **Phase II trial: SIRT + CisGem; 41 patients (32 per-protocol population)**
- Response rate at 3 months of
(locally assessed); 41% at
review)
- According to Choi cr
was 93%
- 22% of patients (9 p
to surgical interventio
- Median progression-free su
months (95% CI, 8-17 months), a
overall survival was 22 months (95% CI, 14-
months)

Proposed clinical trial:
CisGem x 4 cycles – SIRT – CisGem x 4 cycles
Chief Investigator: Alamarca
Countries: Spain, UK, France



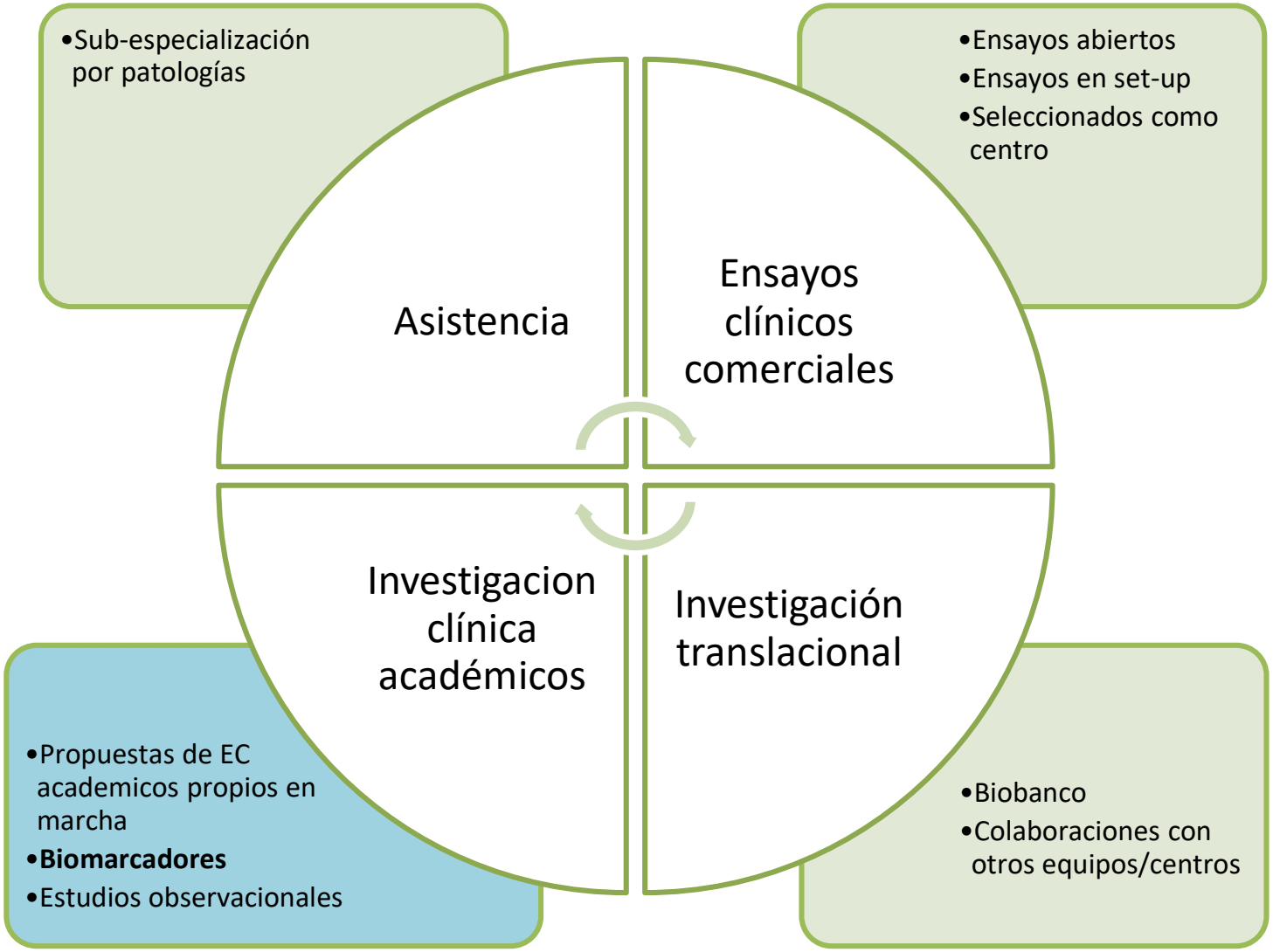
Edeline JAMA Oncol 2019

Early diagnosis in BTC



Proposed clinical trial pending funding

¿Qué hacemos y hacia dónde vamos?



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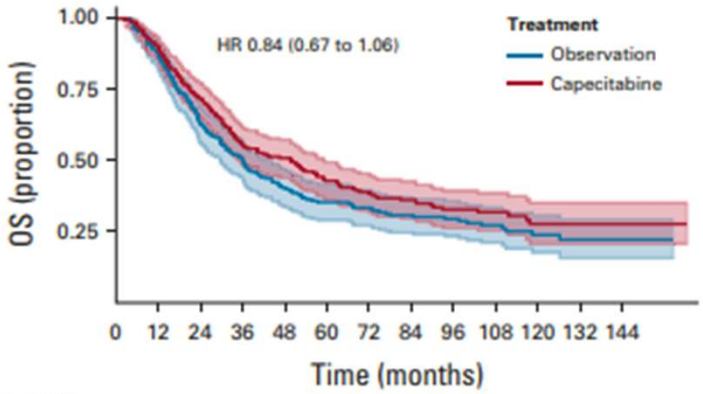
Adjuvant treatment – BilCap

- Cholangiocarcinoma and Gallbladder cancer (ampullary tumours EXCLUDED)
- Randomised phase III: Capecitabine vs Observation (n=447)
  - Primary end-point: OS (pre-planned sensitivity analysis)

Long-term follow-up (2022)

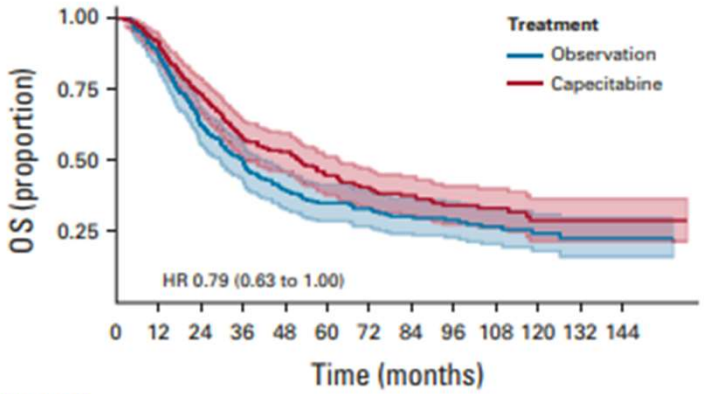
A



No. at risk:

Observation													
At risk	224	193	136	109	87	76	64	54	41	28	18	9	2
Censored	0	3	6	7	7	7	15	20	31	41	48	56	63
Events	0	28	82	108	130	141	145	150	152	155	158	159	159
Capecitabine													
At risk	223	195	155	118	108	91	73	60	43	28	17	8	4
Censored	0	6	7	9	9	9	19	27	39	53	61	70	74
Events	0	22	61	96	106	123	131	136	141	142	145	145	145

B



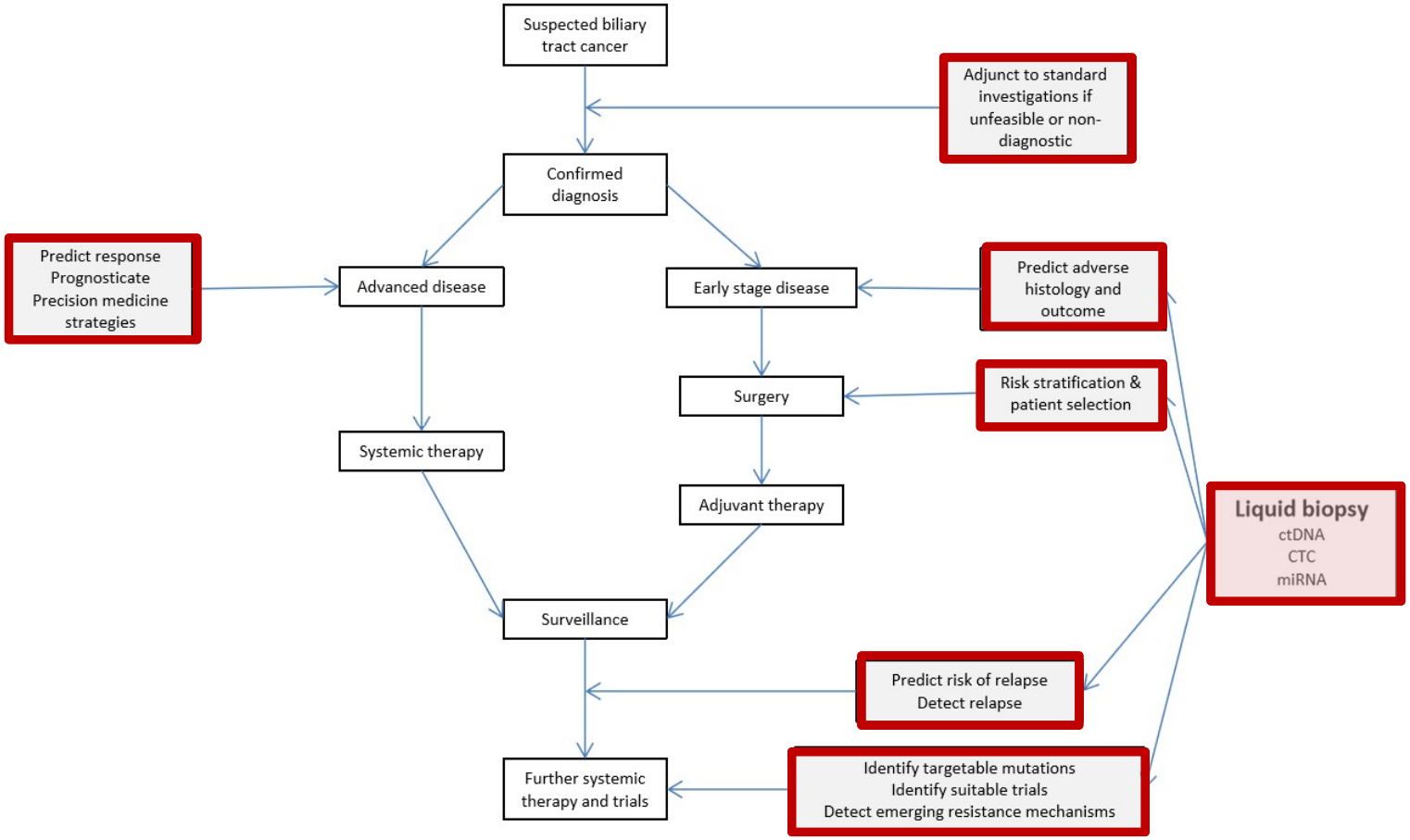
No. at risk:

Observation													
At risk	220	190	133	106	84	74	62	52	39	27	18	9	2
Censored	0	3	6	7	7	7	15	20	31	40	47	55	62
Events	0	27	81	107	129	139	143	148	150	153	155	156	156
Capecitabine													
At risk	210	190	152	118	108	91	73	60	43	28	17	8	4
Censored	0	2	3	5	5	5	15	23	35	49	57	66	70
Events	0	18	55	87	97	114	122	127	132	133	136	136	136

Benefit

Long-term follow-up confirms benefit from Capecitabine in this setting

Potential utility of ctDNA



Shotton et al, World Journal of Gastrointestinal Oncology 2021

Potential utility of ctDNA: post-surgery

- **Preliminary data: ctDNA after curative surgery could identify patients at high risk of recurrence with shorted DFS (n=11)**

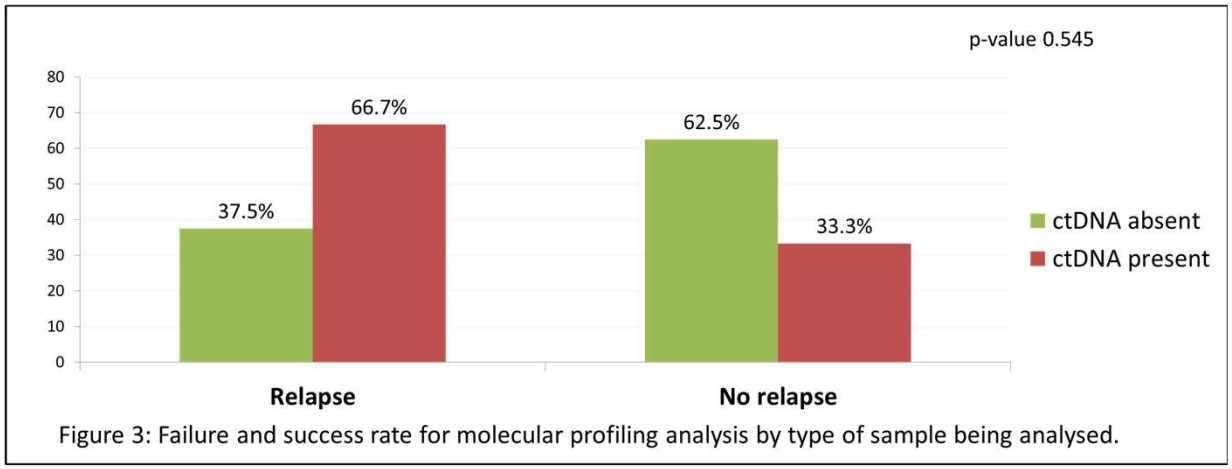
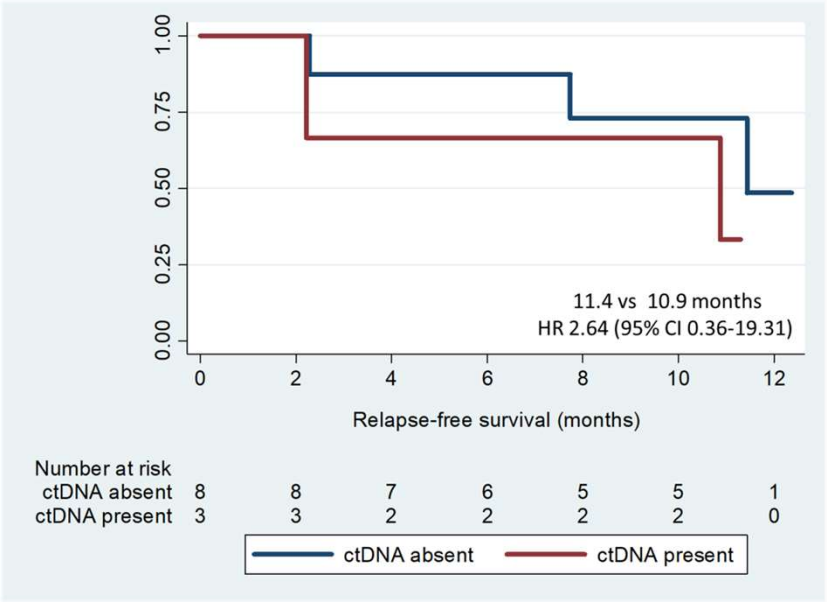


Figure 3: Failure and success rate for molecular profiling analysis by type of sample being analysed.



Lamarca et al, ASCO GI 2021

MRD in BTC: study proposal

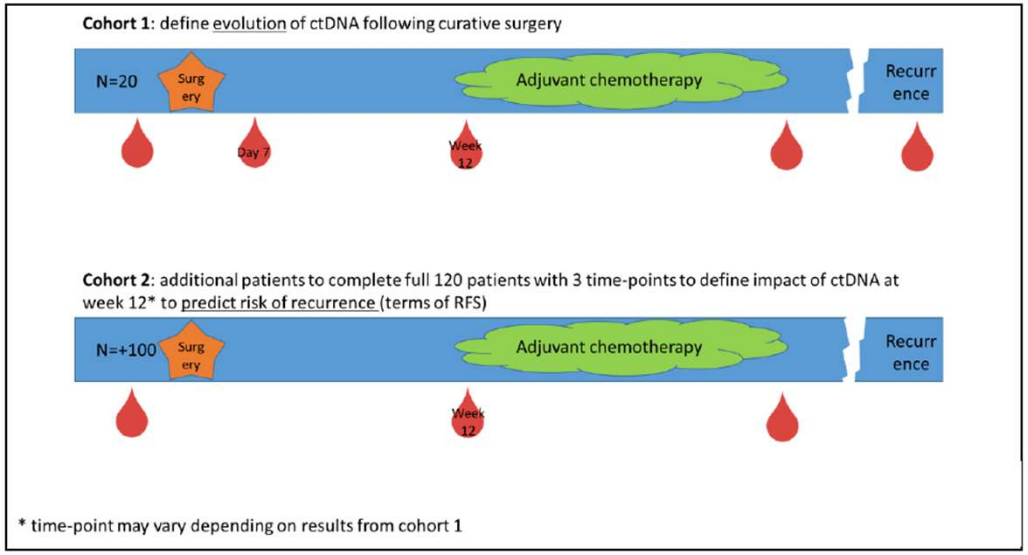


Figure 2: Study schema.

4) METHODOLOGY

The aim of the proposed study is to develop ctDNA as a biomarker to be used for risk stratification following curative surgery of pancreas and biliary tract malignancies (role for identification of minimal residual disease (MRD))

Proposed study design: This will be a multicentre observational prospective trial. Inclusion criteria: all patients due to undergo curative surgery for resectable biliary tract (cholangiocarcinoma, gallbladder cancer and ampullary cancer) or pancreatic cancer. If patients meet inclusion criteria, no exclusion criteria apply.

The study is designed (**Figure 2**) in two separate cohorts:

- Cohort 1: expected to recruit 20 evaluable patients, will aim to define the dynamic evolution of ctDNA following curative surgery (see Figure 2). Patients will have a ctDNA sample tested at 5 different time-points: pre-surgery, day 7 post-surgery, week 12 post-surgery (prior to adjuvant treatment), completion of adjuvant treatment and at time of tumour recurrence.
- Cohort 2: expected to recruit 100 additional evaluable patients, will aim to describe impact of presence of ctDNA on patients' outcome. In this cohort, ctDNA will be measured pre-surgery, week 12* post-surgery (prior to adjuvant treatment) and at completion of adjuvant treatment.

Evaluable patients will be those who:

- cohort 1: all patients recruited;
- cohort 2: patients who had, at least, week 12 sample collected;
- non-evaluable patients will be replaced.

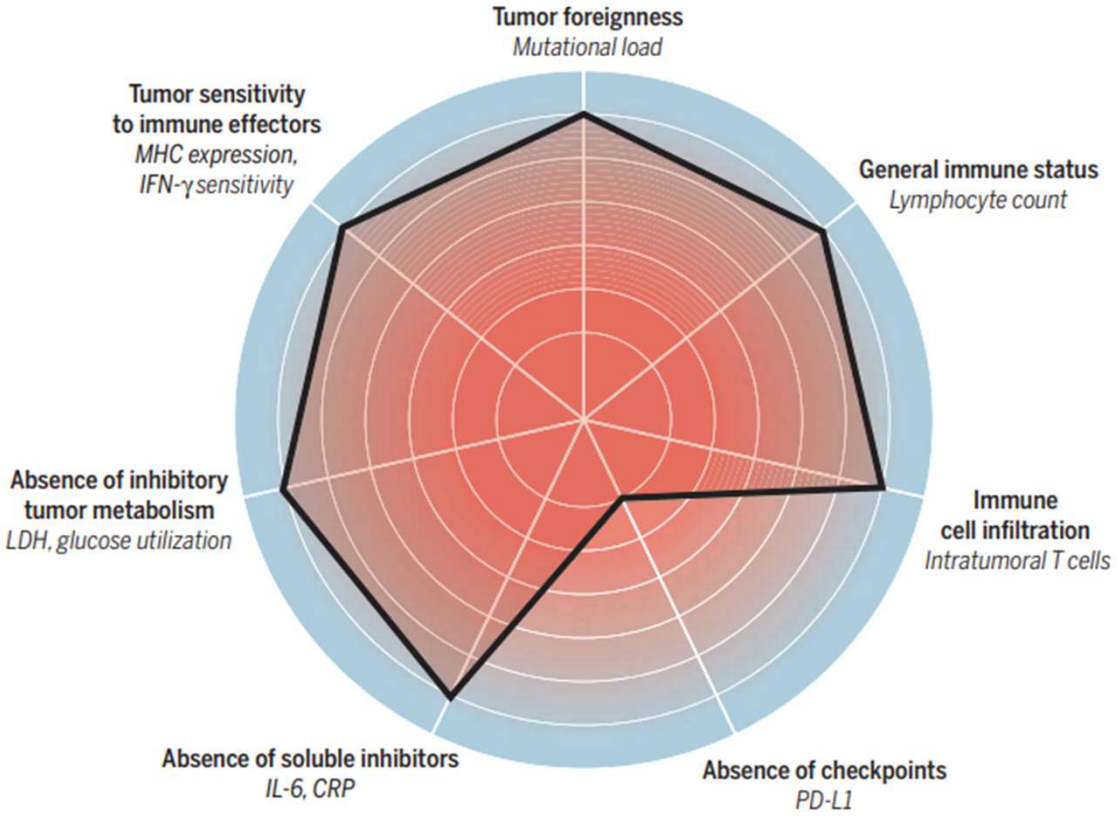
Presence of ctDNA will be defined as the presence of at least 1 pathological mutation/fusion within the panel of cancer-associated genes tested is identified (assuming that ctDNA analysis was successful)

Proposed clinical trial pending funding

Biomarkers for Immunotherapy

"Seven parameter classes may constitute a reasonable initial framework for building such an immunogram..."

"...a cancer immunogram... does make it possible to... discuss treatment options in a more refined and personalized manner..."



The cancer immunogram. The radar plot depicts the seven parameters that characterize aspects of cancer-immune interactions for which biomarkers have been identified or are plausible. Potential biomarkers for the different parameters are shown in italics. Desirable states are located in blue; progressively undesirable states are shown in the red gradient. The black line connecting the data values for each parameter represents a plot for a single hypothetical patient. In the case shown, it may be argued that single-agent PD-1 blockade, rather than combined PD-1 and CTLA-4 blockade, could be a first treatment of choice. For details on this case and other hypothetical patient cases, see (*2*).

Blank et al, Science 2016

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First-line – Durvalumab + CisGem (TOPAZ-1)

- TOPAZ-1: improved ORR/PFS/OS in favour of **Durvalumab + CisGem**

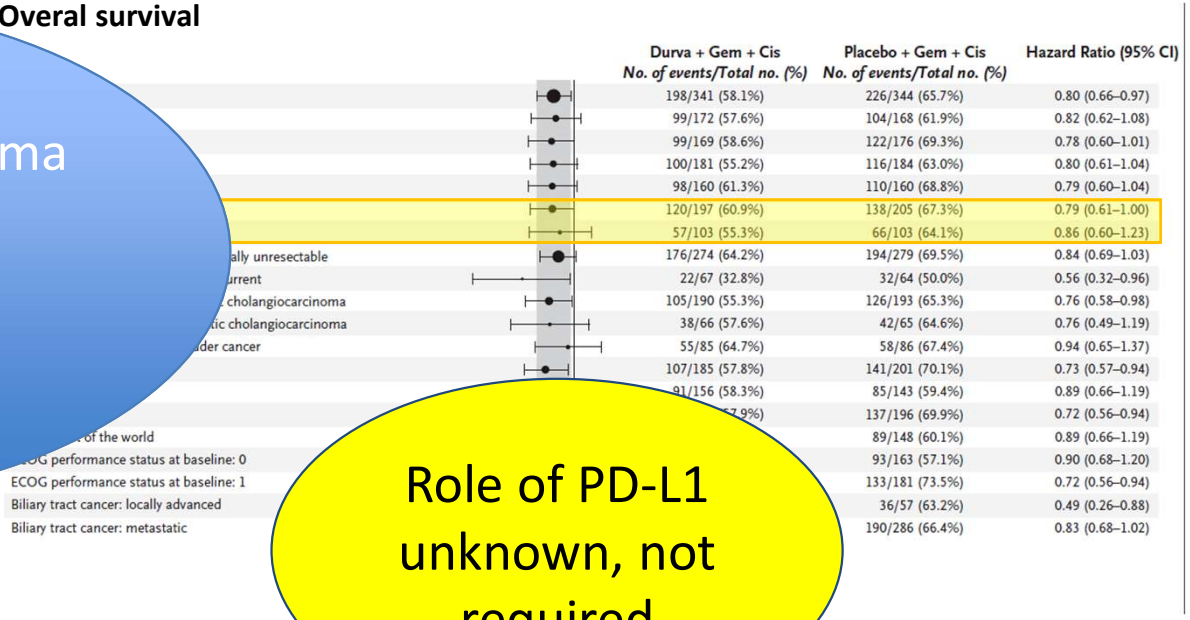
Median OS 12.8 months (CisGem+Durva – TOPAZ-1)
Median PFS 7.2 months (CisGem+Durva – TOPAZ-1)
ORR 26.7% (CisGem+Durva – TOPAZ-1)

Table 2. Tumor Response in the Full Analysis Set.*

Parameter	
Objective response rate — no. (%)†	
Complete response	
Partial response	
Disease control rate — no. (%)‡	
Median duration of response (IQR) — mo§	
Patients with continued response — %	
≥3 mo	
≥6 mo	
≥9 mo	
≥12 mo	
Median time to response (IQR) — mo¶	1.6 (

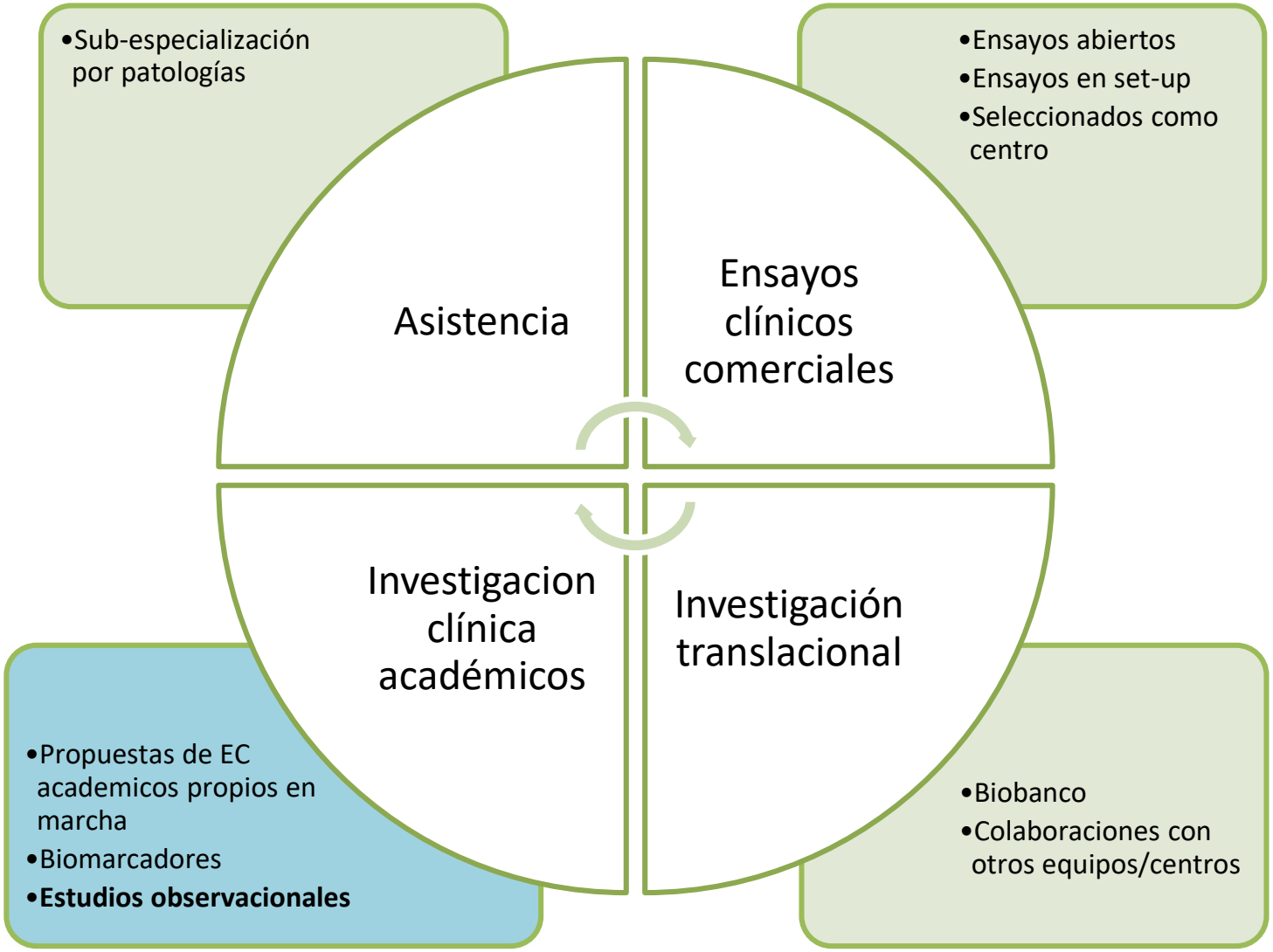
Collaboration with Pharma and VHIO to develop radiomics in BTC (IO-related biomarkers)

Overal survival



Role of PD-L1 unknown, not required

¿Qué hacemos y hacia dónde vamos?



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Spoiler alert!

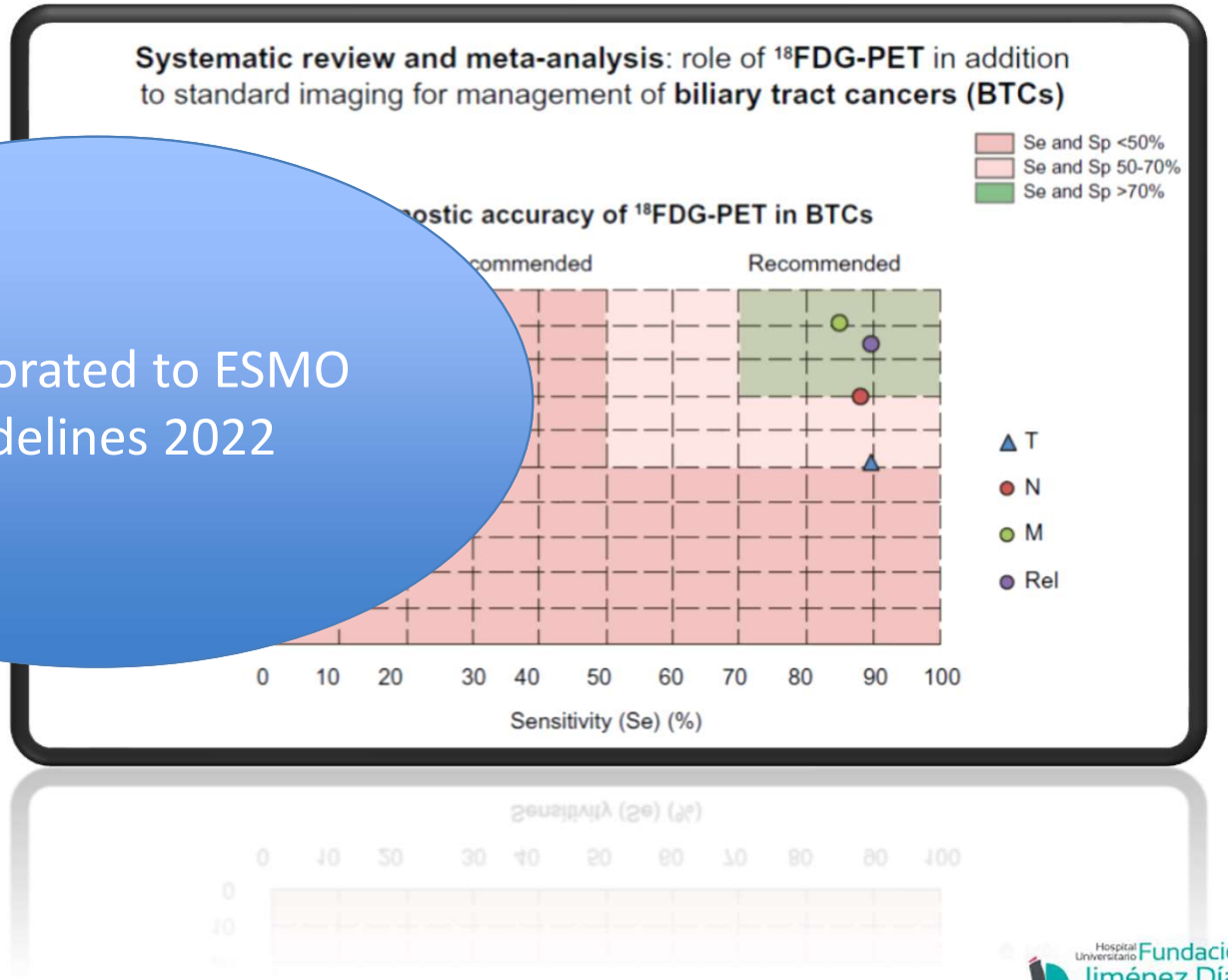
Los studios observacionales/retrospectivos PUEDEN cambiar la practica clinica

Role of ^{18}FDG-PET for diagnosis and staging of BTCs

- Supports ^{18}FDG-PET for the assessment of N, M and Relapse (Rel):
  - if the identification of occult sites of disease would change manageme
    (i.e. surgery/local therapies)
  - if diagnosis of Rel remains
    following standard of car

Incorporated to ESMO guidelines 2022

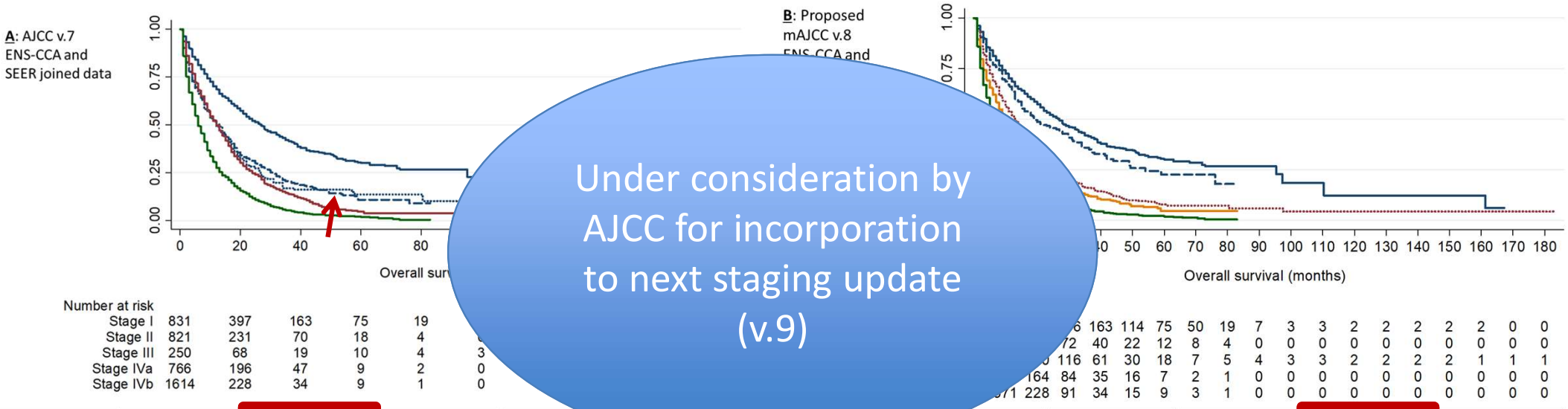
- The use of ^{18}FDG-PET for diag
  primary tumour (T) in the absence
  other disease sites or pathological confirmation remains controversial, due to low specificity.



Lamarca et al, J of Hepatol 2019

Staging of iCCA: liver metastases

- Multifocal liver disease (liver metastases): T2 vs M1

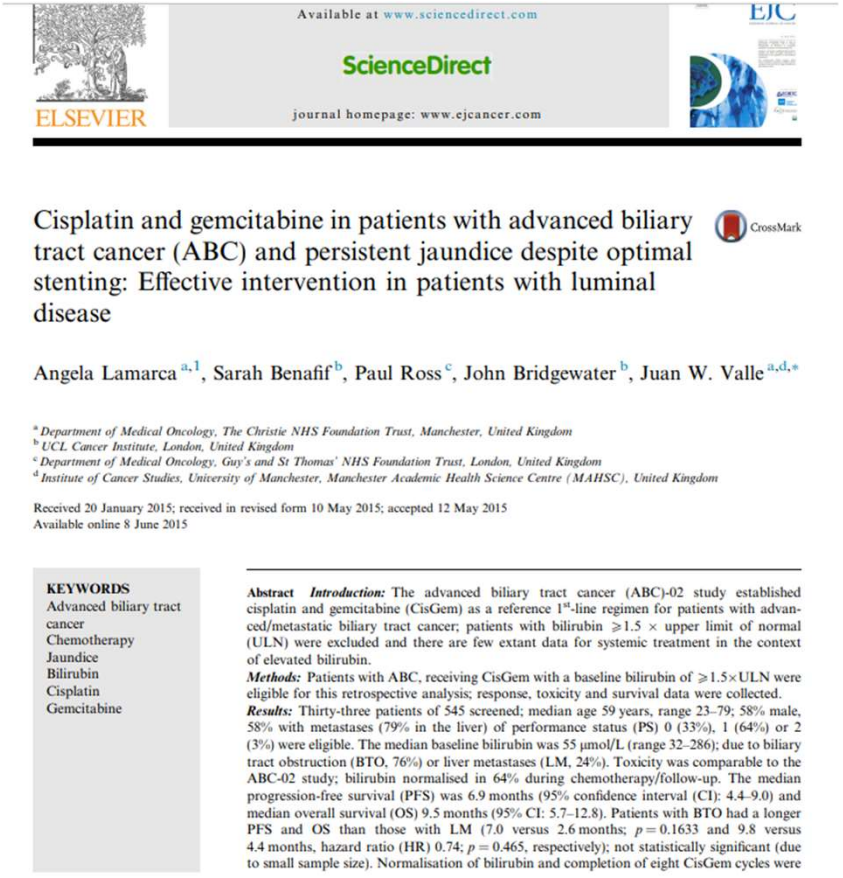


Under consideration by AJCC for incorporation to next staging update (v.9)

Group	Stage I (incl Tis)	Stage II (incl T2bN0M0)	Stage III	Stage IVa (incl T2bN1M0)	
Label	—	—·	····	—	—
% of patients	19.41%	19.17%	5.83%	17.89%	37.69%
Median OS months (95% CI)	27 (23-30)	12 (11-13)	13 (10-15.01)	12 (11-14)	6 (6-7)
Univariate HR (95% CI); p-value	1 (Ref)	1.84 (1.63-2.07); <0.001	1.87 (1.58-2.21); <0.001	32.09 (1.85-2.36); <0.001	3.29 (2.96-3.65); <0.001

	Stage I (T1N0M0)	Stage II (T2N0M0; solitary)	Stage III (T3/4 N0; N1; M0)	Stage IVa (M1a; Liver mts)	Stage Ivb (M1b: extrahepatic mts)
Label	—	—·	·····	—	—
% of patients	19.41%	6.12%	19.15%	17.63%	37.69%
Median OS months (95% CI)	27 (23-30)	19 (15-28)	13 (11.92-14)	10 (9-11)	6 (6-7)
Univariate HR (95% CI); p-value	1 (Ref)	1.21 (1.01-1.45); 0.034	1.94 (1.72-2.18); <0.001	2.33 (2.07-2.63); <0.001	3.31 (2.98-3.68); <0.001
Univariate HR (95% CI); p-value	0.43 (0.38-0.48); <0.001	0.52 (0.44-0.62); <0.001	0.83 (0.74-0.93); 0.001	1 (Ref)	1.42 (1.29-1.56); <0.001

CisGem in Jaundiced BTC patients



Available at www.sciencedirect.com

ScienceDirect

journal homepage: www.ejcancer.com

Cisplatin and gemcitabine in patients with advanced biliary tract cancer (ABC) and persistent jaundice despite optimal stenting: Effective intervention in patients with luminal disease

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Abstract ***Introduction:*** The advanced biliary tract cancer (ABC)-02 study established cisplatin and gemcitabine (CisGem) as a reference 1st-line regimen for patients with advanced/metastatic biliary tract cancer; patients with bilirubin ⩾1.5 × upper limit of normal (ULN) were excluded and there are few extant data for systemic treatment in the context of elevated bilirubin.
Methods: Patients with ABC, receiving CisGem with a baseline bilirubin of ⩾1.5×ULN were eligible for this retrospective analysis; response, toxicity and survival data were collected.
Results: Thirty-three patients of 545 screened; median age 59 years, range 23–79; 58% male, 58% with metastases (79% in the liver) of performance status (PS) 0 (33%), 1 (64%) or 2 (3%) were eligible. The median baseline bilirubin was 55 μmol/L (range 32–286); due to biliary tract obstruction (BTO, 76%) or liver metastases (LM, 24%). Toxicity was comparable to the ABC-02 study; bilirubin normalised in 64% during chemotherapy/follow-up. The median progression-free survival (PFS) was 6.9 months (95% confidence interval (CI): 4.4–9.0) and median overall survival (OS) 9.5 months (95% CI: 5.7–12.8). Patients with BTO had a longer PFS and OS than those with LM (7.0 versus 2.6 months; $p = 0.1633$ and 9.8 versus 4.4 months, hazard ratio (HR) 0.74; $p = 0.465$, respectively); not statistically significant (due to small sample size). Normalisation of bilirubin and completion of eight CisGem cycles were

For PS 0-1 patients with ABC and high bilirubin due to luminal disease despite optimal stenting CisGem can be used safely with results similar to those in patients with normal bilirubin.

Incorporated to ESMO guidelines 2022

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Lamarca et al EJC 2014

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Stent-related events

- HPB (including BTC) patients with metal stent are at high risk of new stent related event (SRE)
  - 43% of patients will have at least 1 SRE
    - Median time-to-SRE was 4.4
    - Cholangitis 39%
    - Stent obstruction 2
    - Both 32%
    - Further events 34%
- Proactive management of these required: **Biliary obstruction is a medical emergency!**

Table 3 Risk of development of stent-related event increased with longer follow-up period in the absence of competing event (death)

Time-point of follow-up since first biliary stenting	Estimated risk of development of SRE rate for all patients
3 mo	11.5% (95%CI: 6.5-19.7)
6 mo	32.0% (95%CI: 23.5-42.7)
	48.6% (95%CI: 37.5-61)
	59.9% (95%CI: 44-76.5)
	79.9% (95%CI: 48.03-98.1)

Benchmark data for trial design (malignant biliary obstruction)

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Forner A, et al. *Liver International.* 2019;39:98–107; Lamarca et al WJG 2016

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¿Qué hacemos y hacia dónde vamos?

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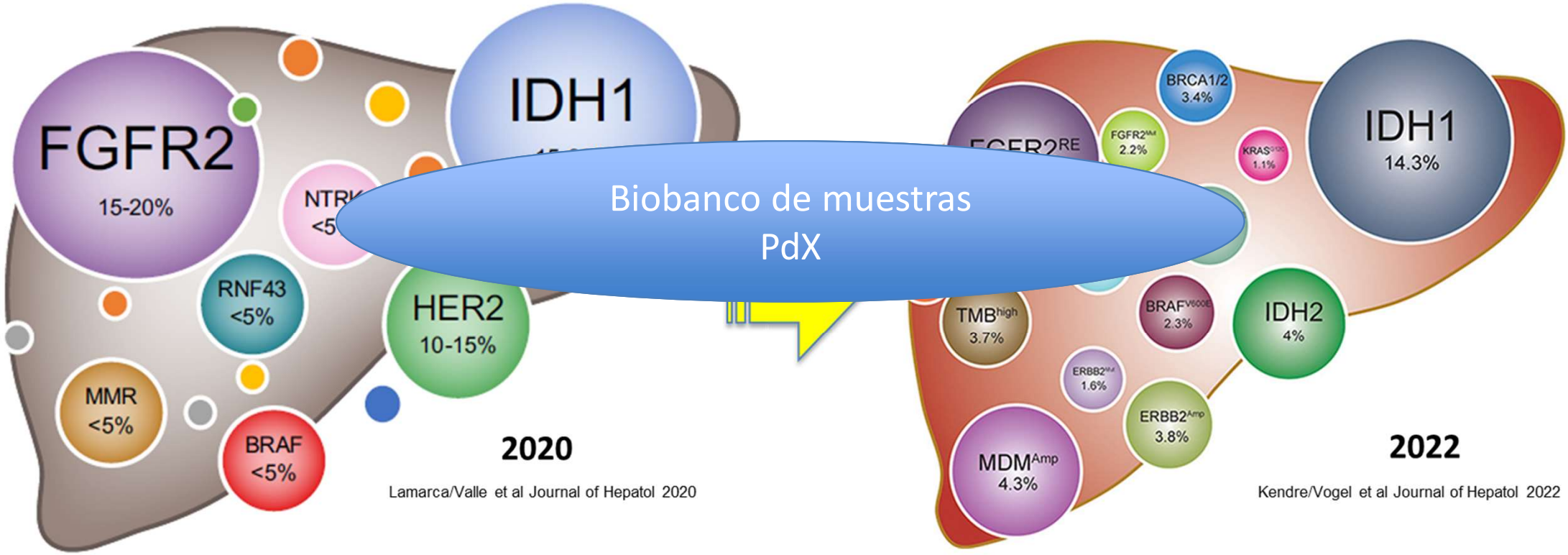
BTC: Precision Medicine is a dynamic field

The field is rapidly evolving

MORE targetable alterations **available** and **BETTER** understanding of their real **prevalence**



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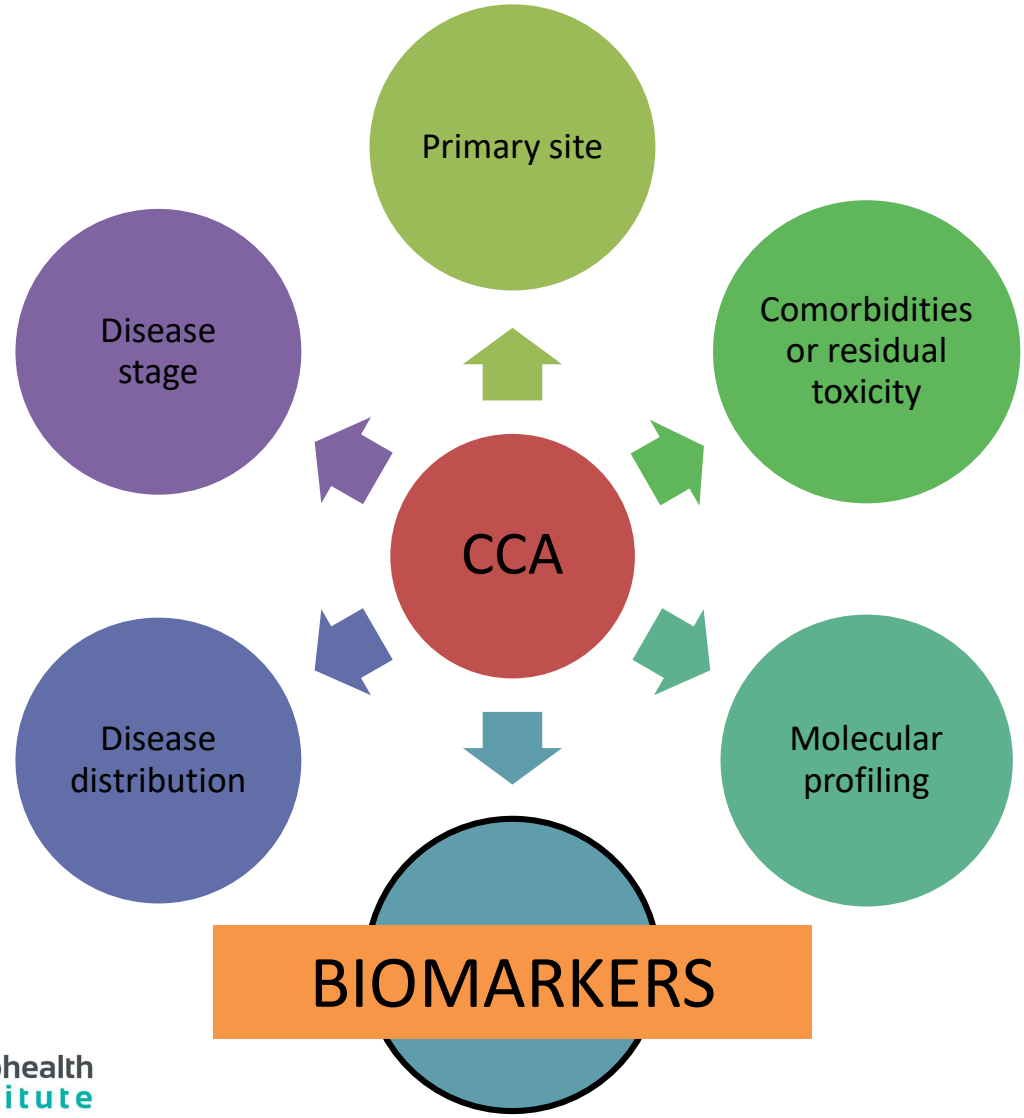
Clinical Decision Making in Advanced CCA



Biomarkers are Urgently needed!

Adjuvant setting

First-line (IO benefit)

Second-line (platinum?)

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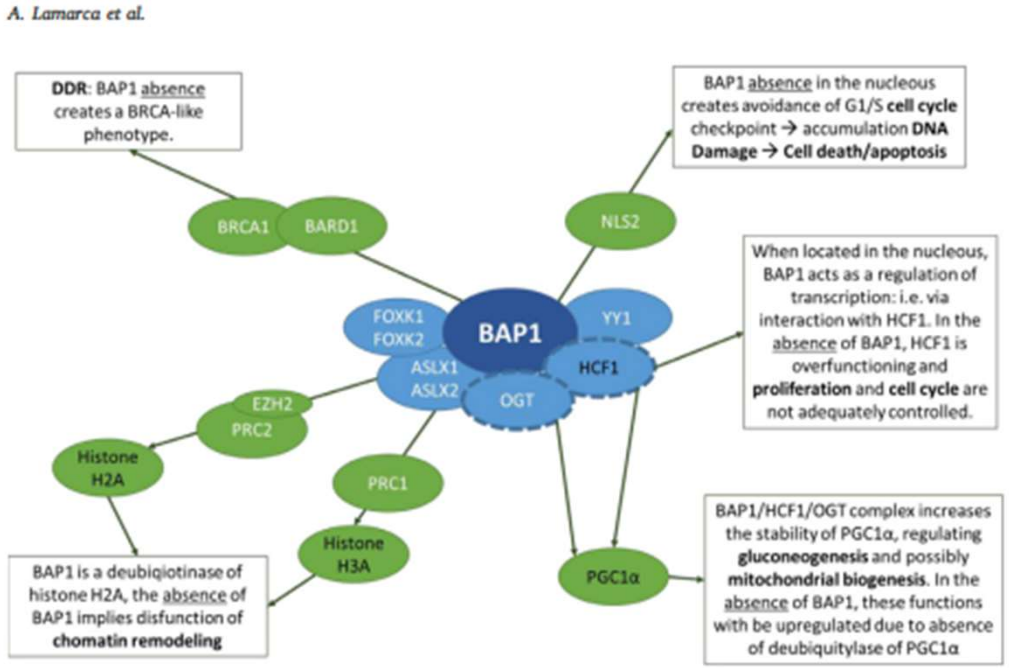
Tailoring chemotherapy options: DDR

- Deficiency of DNA Damage Repair mechanism (dDDR) is present in ~15-20% of BTC.
- Platinum-based chemotherapy may achieve increased response rate in the presence of dDDR
- Impact on PFS/OS
- BAP-1: “BAP-1 alterations in patients with biliary tract Tumours: international Study to assess clinical, therapeutic and molecular implications”



SEOM Beca de Retorno 2022

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Xiao et al, ESMO 2020; Chae EJC 2019; Lamarca et al, JCM 2020; Lamarca et al Cancer Treat Rev .

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CONQUER CANCER FOUNDATION of the American Society of Clinical Oncology
YOUNG INVESTIGATOR AWARD

THE cholangiocarcinoma FOUNDATION

SEOM Sociedad Española de Oncología Médica

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Other funding

CANCER RESEARCH UK

PANCREATIC CANCER UK

pancreatic cancer research fund

STAND UP TO CANCER

AMMF THE CHOLANGIOCARCINOMA CHARITY

Horizon 2020

¿Quiénes somos?

- Medical Oncolgoist:
  - Dr Angela Lamarca MD, PhD, MSc
  - Dr Eva Ruiz MD
  - Dr Raquel Fuentes MD

¡El equipo de oncologia digestiva esta dipueso a colaborar CON TODOS y a ser un ALIADO!

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Thank you for your attention

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