

XXV Encuentro de Cooperación Farma-Biotech

3 de julio de 2025

PH-Care: Biomarker signature for early diagnostic of portal hypertension

ciber

ID **BAPS**

 Clínic
Barcelona

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 MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

biocat

farma|industria

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1. The Institution



Fundació Recerca Clínic Barcelona – IDIBAPS

Centre Esther Koplowitz



Liver Vascular Biology research group

PI: Jordi Gracia-Sancho

Expertise: vascular liver diseases at both pre-clinical and clinical levels.

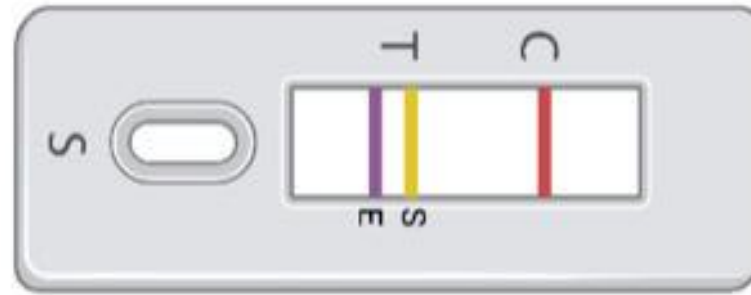
Focus:

- Knowledge of the pathophysiology of the main complications of chronic liver diseases such as portal hypertension
- To identify new therapeutic targets.
- To develop non-invasive biomarkers to improve patients' management.

2. The Product – PH Care

a) Target Indications

PH-Care



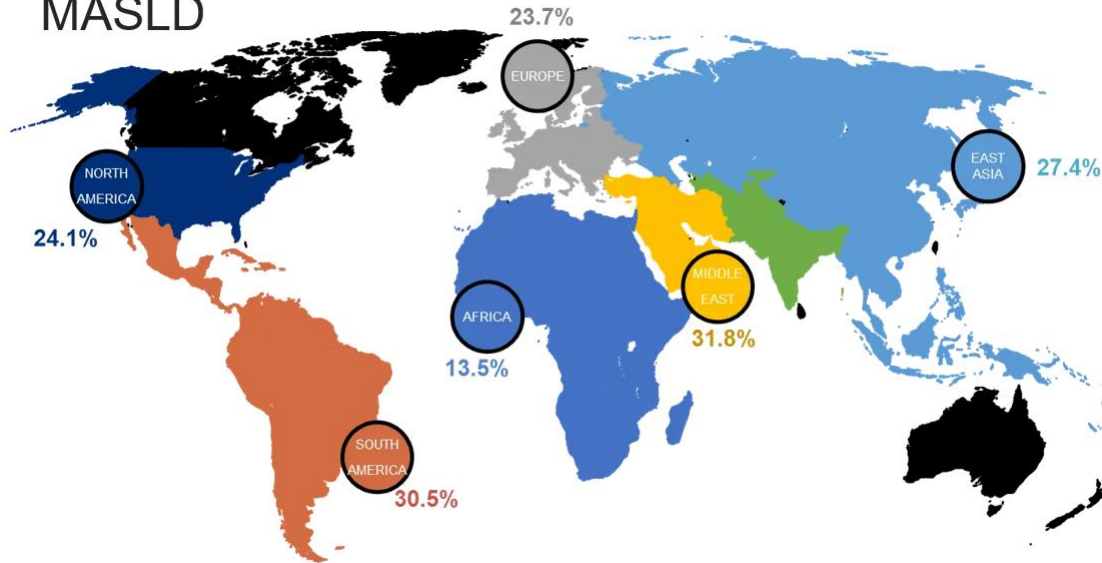
Point of care assay for the **estimation of portal pressure** using a blood sample

2. The Product – PH Care

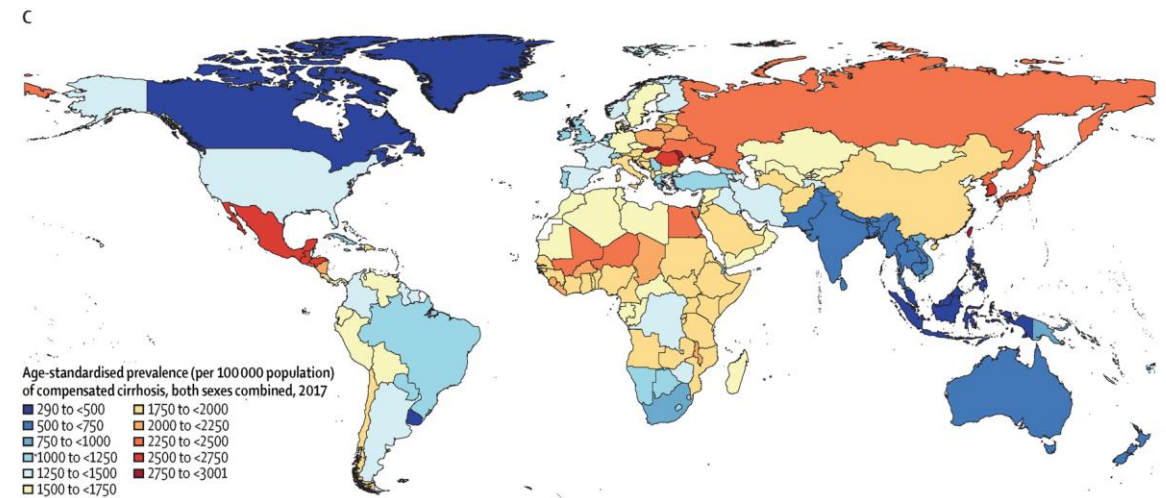
a) Target Indications - Why do we need it?

Liver Diseases

MASLD



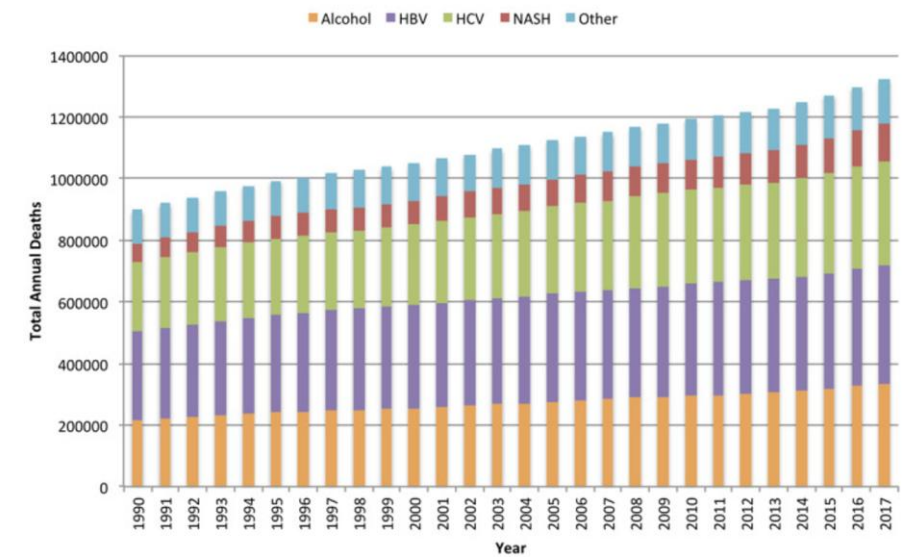
Cirrhosis



Some facts:

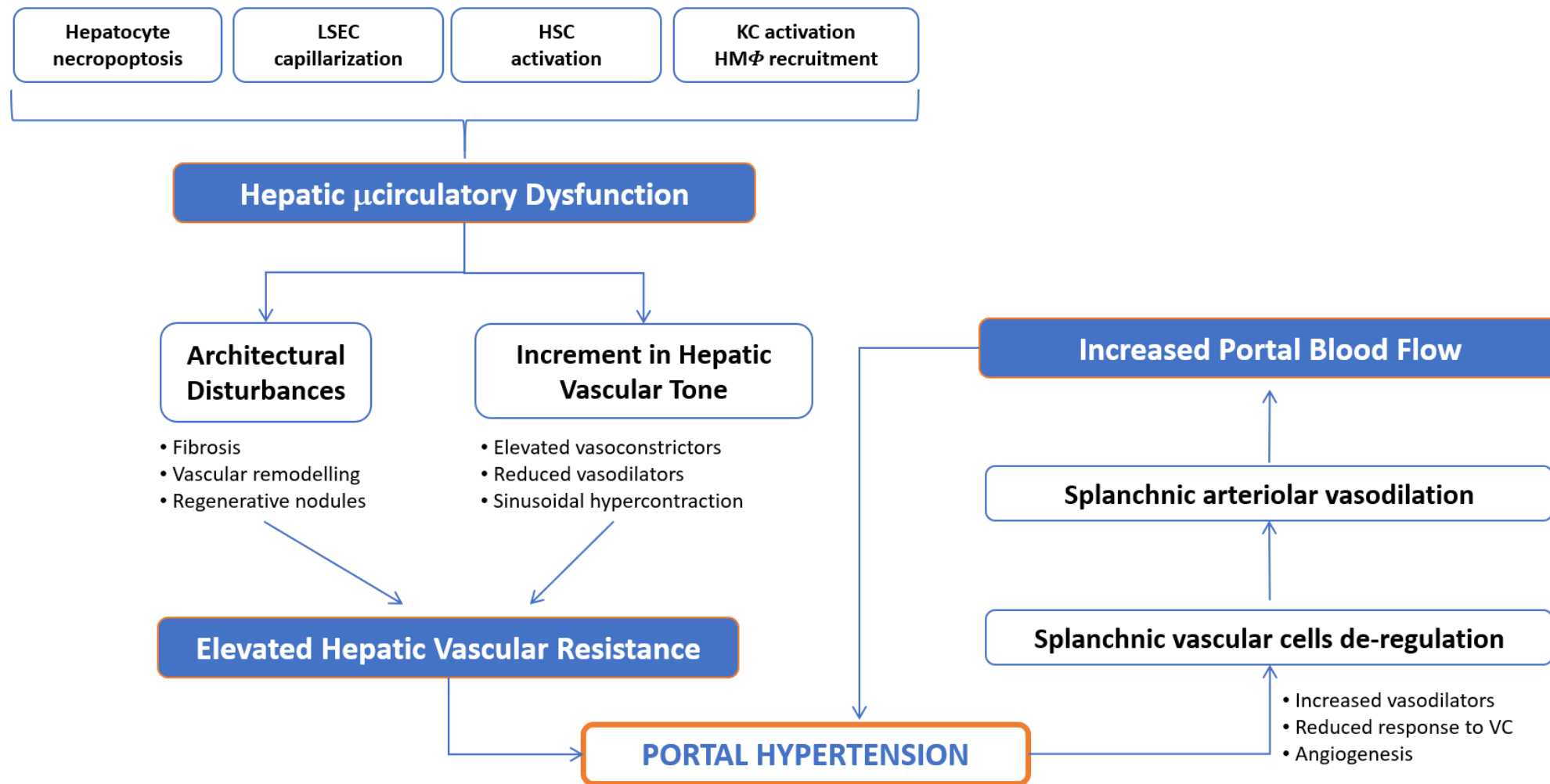
People living with HBV: 260 million
Steatotic liver disease >25% of world population
2% of US population diagnosed with a liver condition
9th cause of mortality in developed countries
No approved treatment (except HCV)

Total Annual Deaths from Cirrhosis, by Etiology



2. The Product – PH Care

a) Target Indications - Why do we need it?



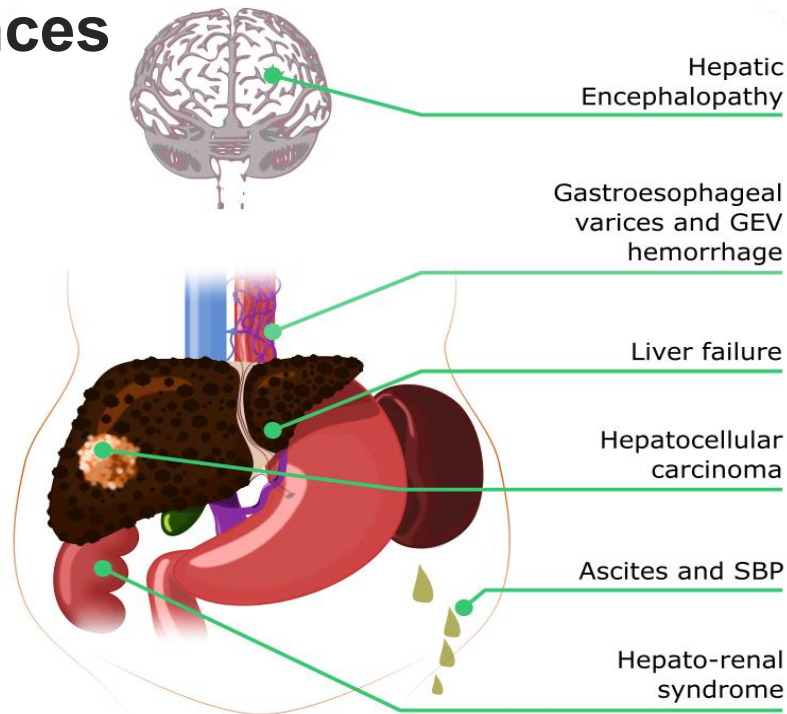
2. The Product – PH Care

a) Target Indications - Why do we need it?

Portal Hypertension

Clinical syndrome very frequent in cirrhosis characterized by a pathological increase in the portal pressure gradient or HVPG (>5 mmHg)

Consequences



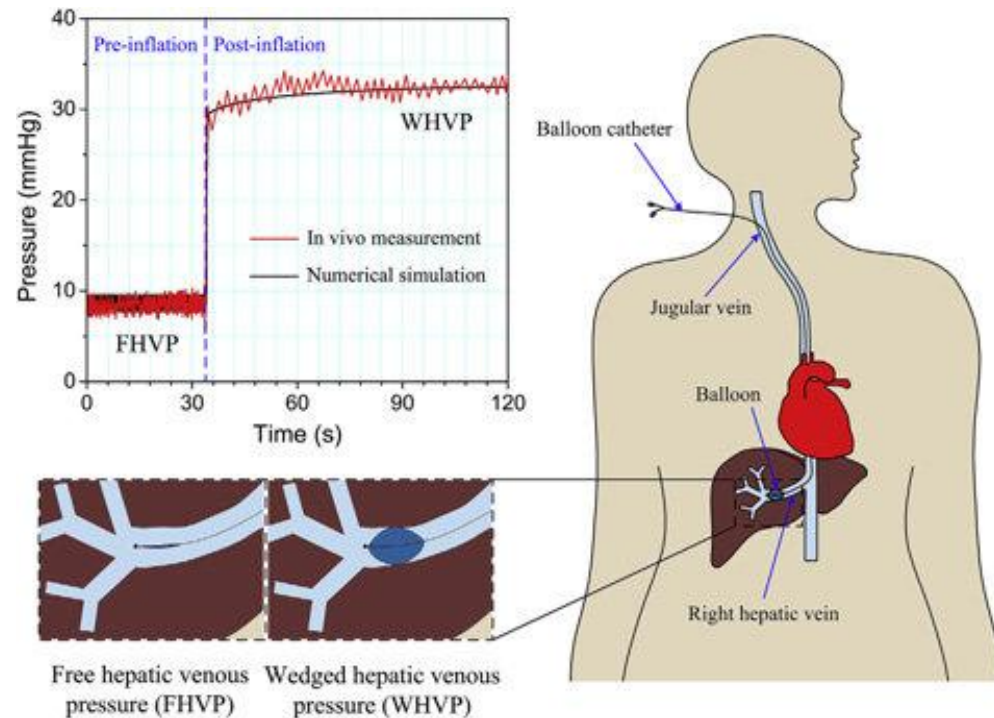
170.000 deaths/year in the EU

1.300.000 deaths/year worldwide

2. The Product – PH Care

a) Target Indications - Why do we need it?

Current method: HVPG



Invasive

Requires hospitalization

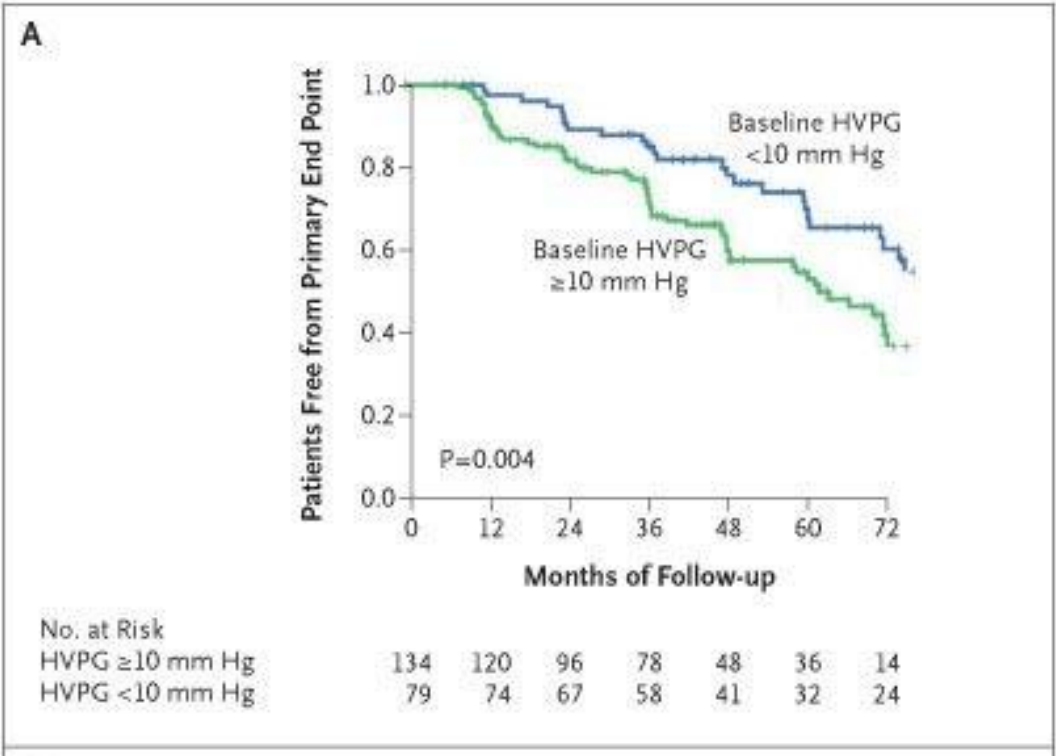
3.500 €/patient

Specialized team (not available in most hospitals)

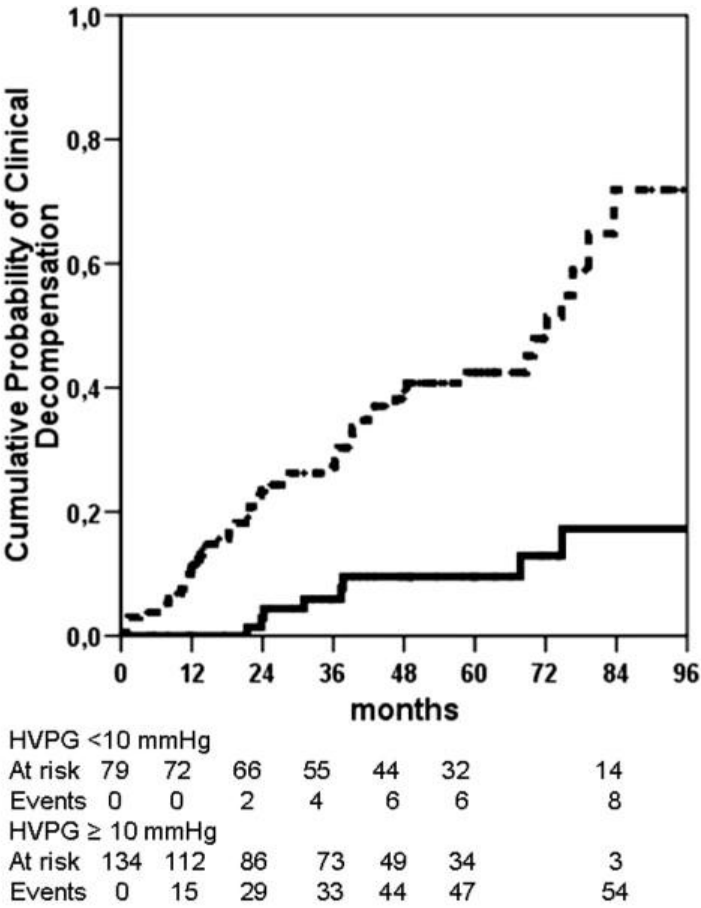
2. The Product – PH Care

a) Target Indications - Why do we need it?

Portal Hypertension & Liver Disease Prognosis



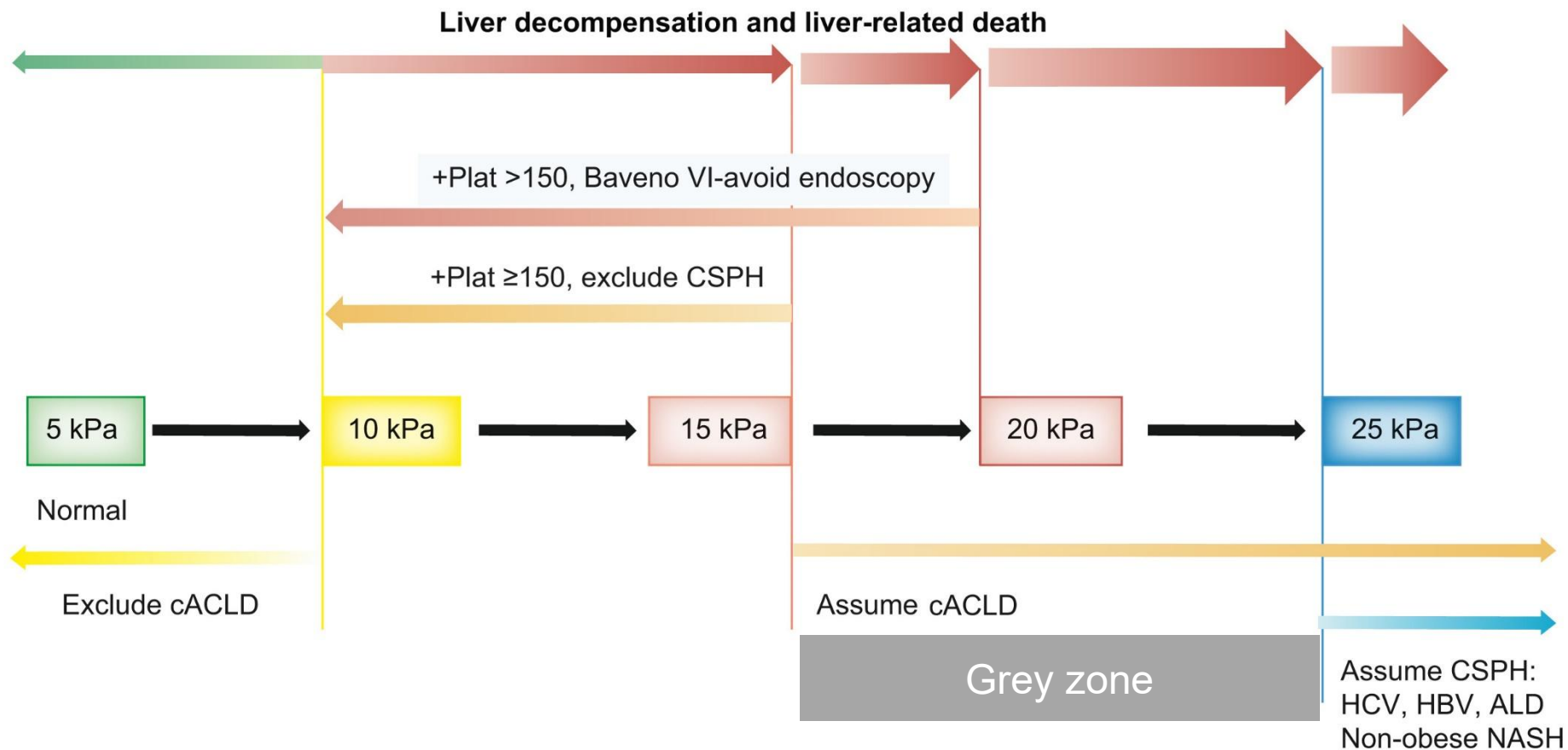
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2. The Product – PH Care

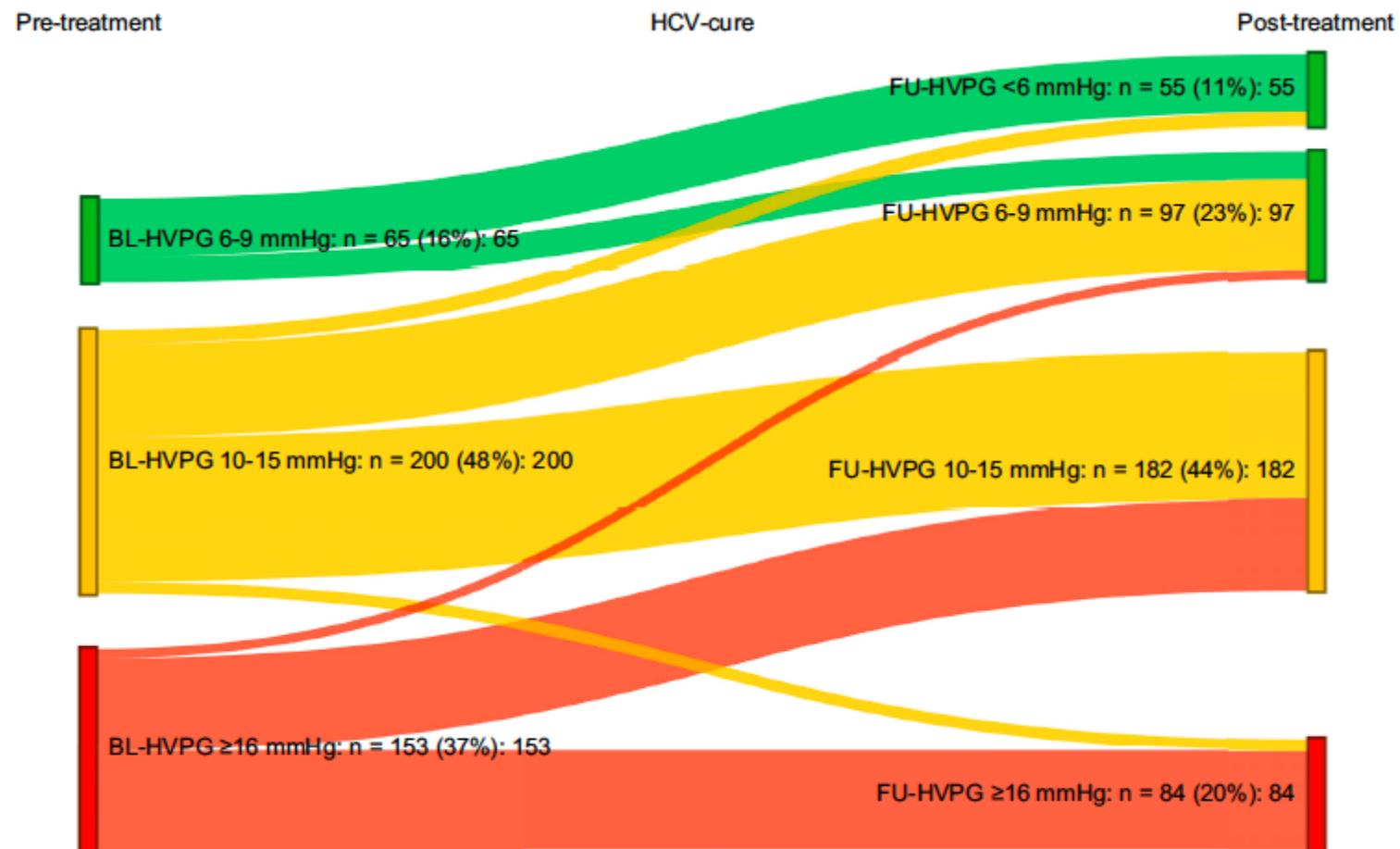
a) Target Indications - Why do we need it?

Alternatives to HVPG measurement



2. The Product – PH Care

a) Target Indications - Why do we need it?



2. The Product – PH Care

a) Target Indications - Why do we need it?

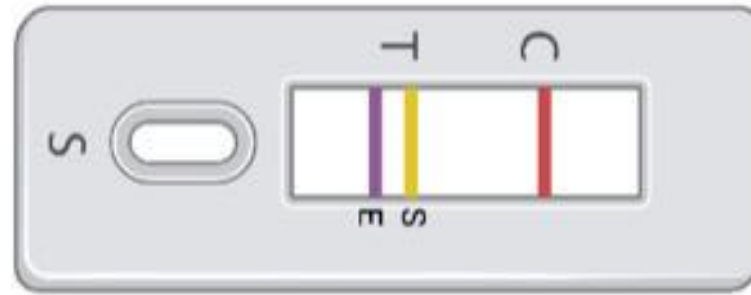
Summary

- PH represents the most important clinical complication of CLD, affecting millions worldwide.
- Prompt diagnosis of PH significantly improves patients prognosis.
- Gold-standard method for PH assessment is invasive, expensive and not available in all centers.
- Non-invasive tests offer alternatives but significant number of patients will ultimately require HVPG measurement.
- There is a high medical need of reliable non-invasive tests for PH and CSPH.

2. The Product – PH Care

a) Target Indications

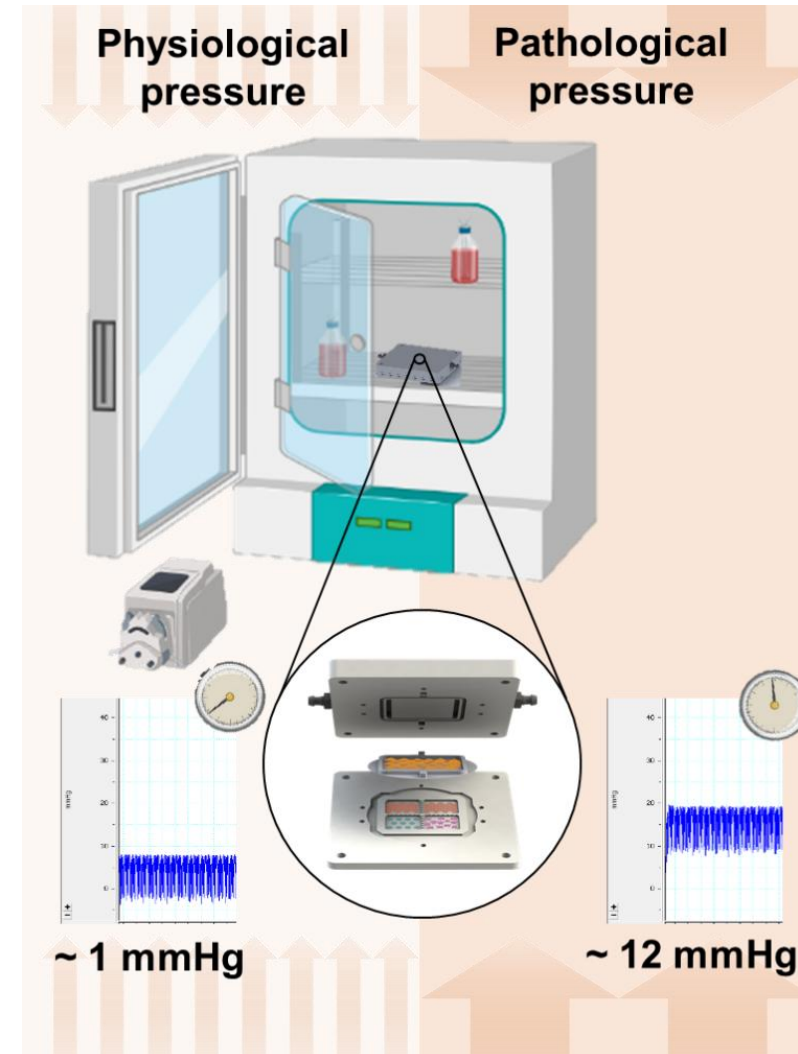
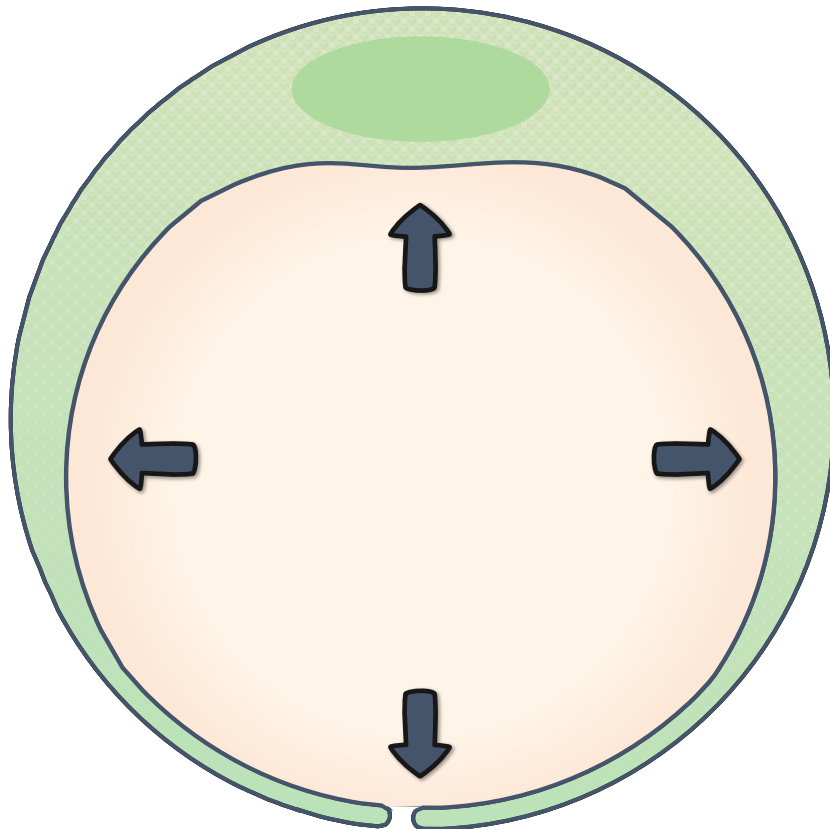
PH-Care



Point of care assay for the **estimation of portal pressure** using a blood sample

2. The Product – PH Care

b) Innovative mechanisms of action



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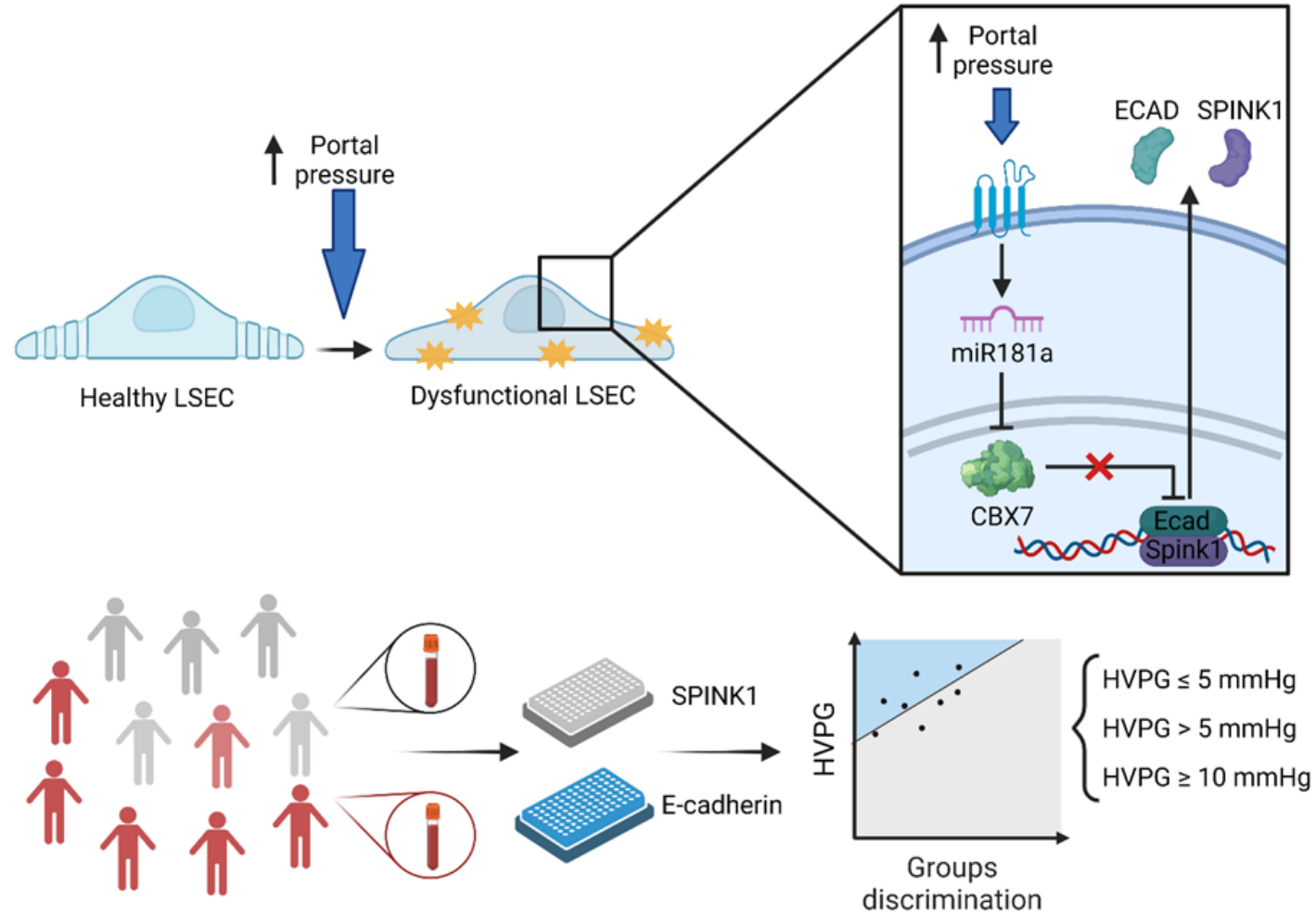
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IMB

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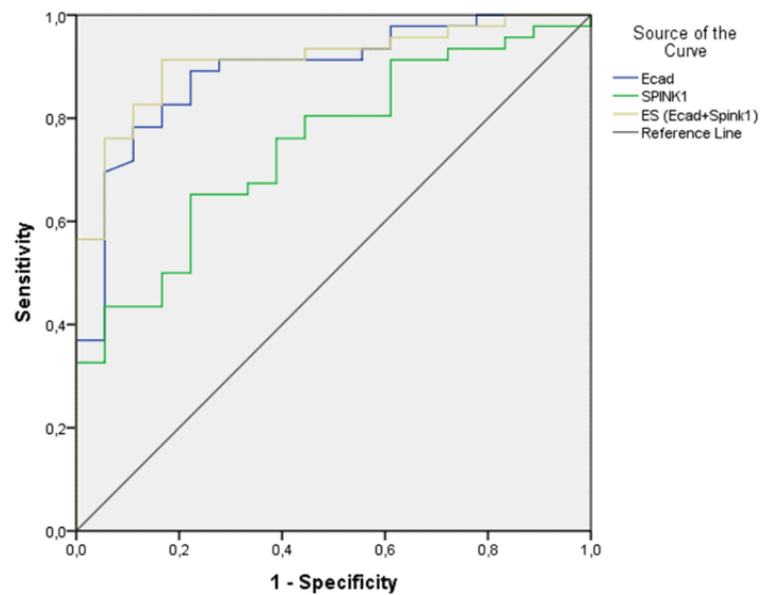
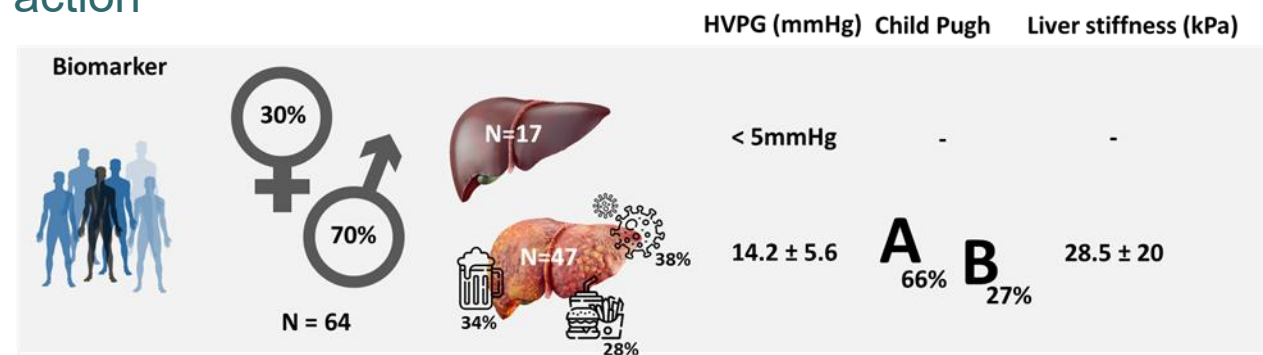
2. The Product – PH Care

b) Innovative mechanisms of action



2. The Product – PH Care

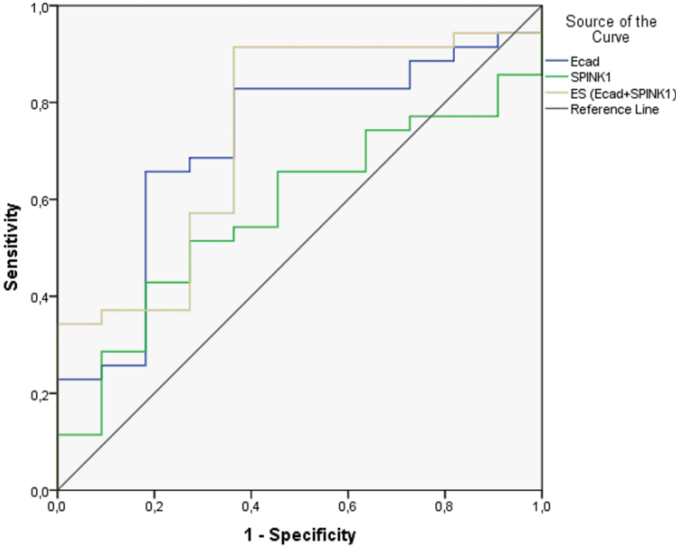
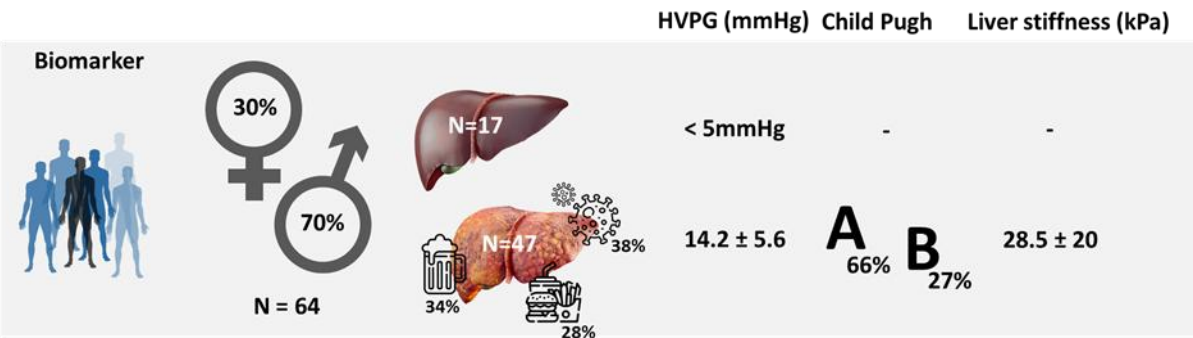
b) Innovative mechanisms of action



Marker	n (</> 5mmHg)	AUROC (95% CI)	Cut-off	Sens (%)	Spec (%)	PPV (%)	NPV (%)
ECAD	18/46	0.889 (0.802 to 0.977)	57.673	89.1	77.8	91.12	73.64
SPINK1	18/45	0.747 (0.622 to 0.871)	16.040	80.0	55.6	81.83	52.65
ECAD + SPINK1	18/46	0.911 (0.838 to 0.983)	0.579	91.3	83.3	93.32	78.93

2. The Product – PH Care

b) Innovative mechanisms of action



Validated in an external cohort

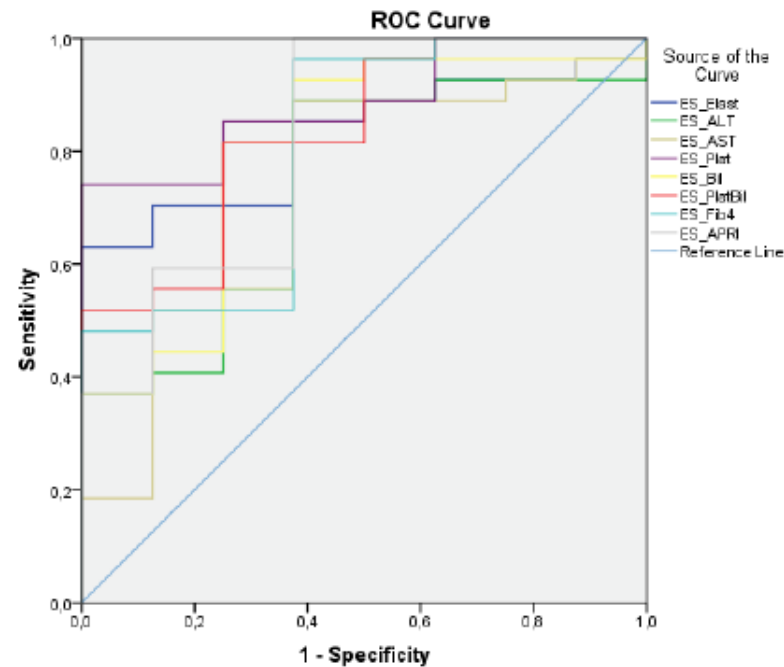
Marker	n (</>10 mmHg)	AUROC (95% CI)	Cut-off	Sens (%)	Spec (%)	PPV (%)	NPV (%)
ECAD	11/36	0.725 (0.557 to 0.893)	73.731	83.3	63.6	88.22	53.78
SPINK1	11/35	0.577 (0.401 to 0.752)	20.765	65.7	54.5	82.13	33.31
ECAD + SPINK1	11/35	0.738 (0.564 to 0.911)	0.647	91.4	63.6	88.88	69.92

2. The Product – PH Care

b) Innovative mechanisms of action

Combination of ES + current diagnostic tests

B



Parameter	n (</>10 mmHg)	AUROC (95% CI)	Cut-off	Sens (%)	Spec (%)	PPV (%)	NPV (%)
ES_Elast	8/27	0.824 (0.686-0.962)	0.588	85.2	62.5	88.5	55.6
ES_ALT	8/27	0.736 (0.542-0.93)	0.652	88.9	62.5	88.9	62.5
ES_AST	8/27	0.727 (0.52-0.934)	0.622	88.9	62.5	88.9	62.5
ES_Plaf	8/27	0.884 (0.773-0.996)	0.701	85.2	75.0	92.0	60.0
ES_Bil	8/27	0.801 (0.617-0.984)	0.644	81.5	75.0	91.7	54.5
ES_PlafBil	8/27	0.833 (0.68-0.987)	0.646	81.5	75.0	91.7	54.5
ES_Fib4	8/27	0.806 (0.625-0.987)	0.582	96.3	62.5	92.9	85.7
ES_APRI	8/27	0.819 (0.637-1.000)	0.572	100	62.5	90	100

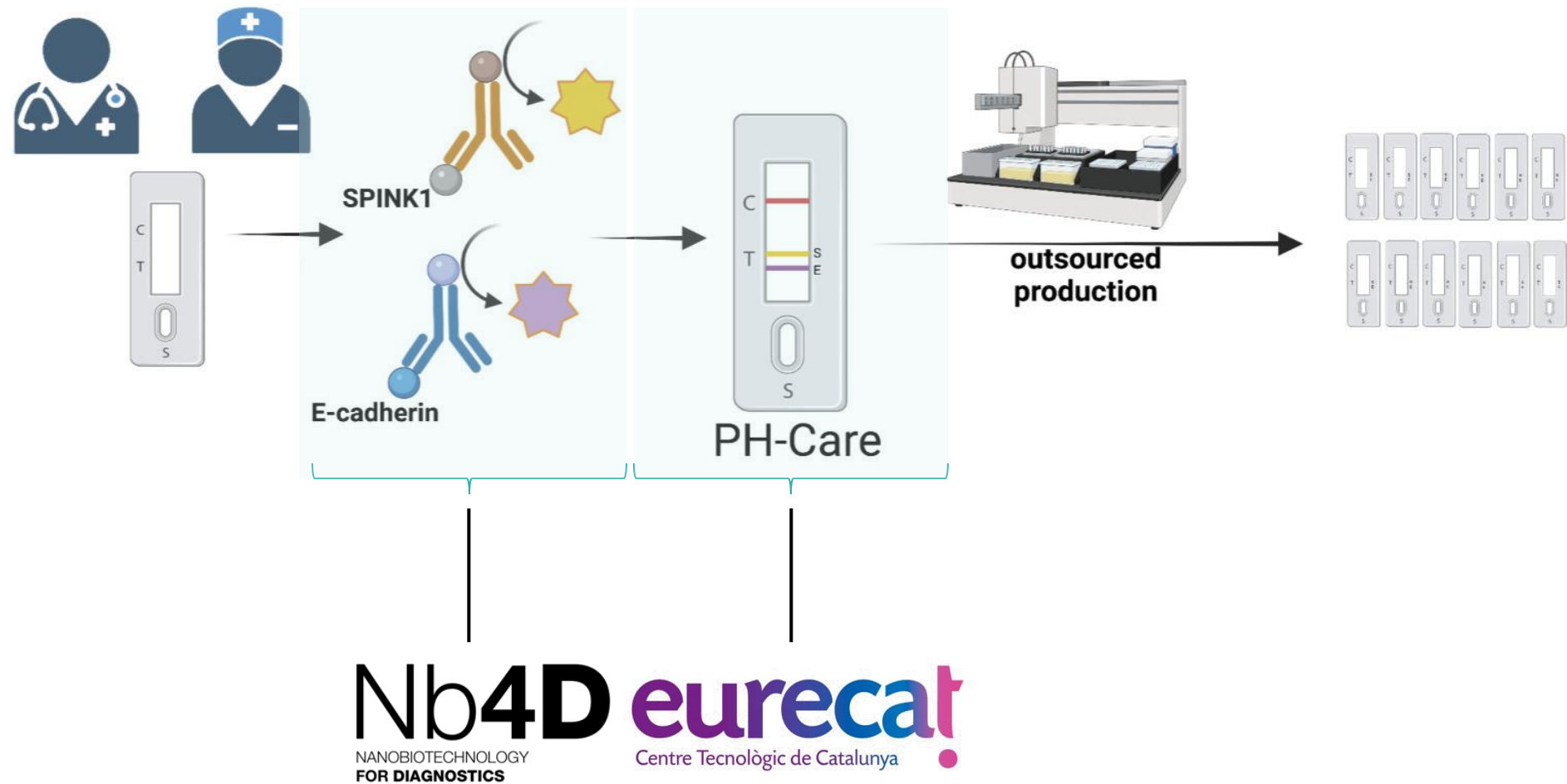
2. The Product – PH Care

c) Differential features facing the market

- Cheaper, more accessible, safer, less invasive than HVPG.
- Superior performance than other non-invasive surrogates of HVPG.
- Directly reflects the biology of portal hypertension and endothelial cells.
- May be relevant detecting regression of portal hypertension and cirrhosis.

2. The Product – PH Care

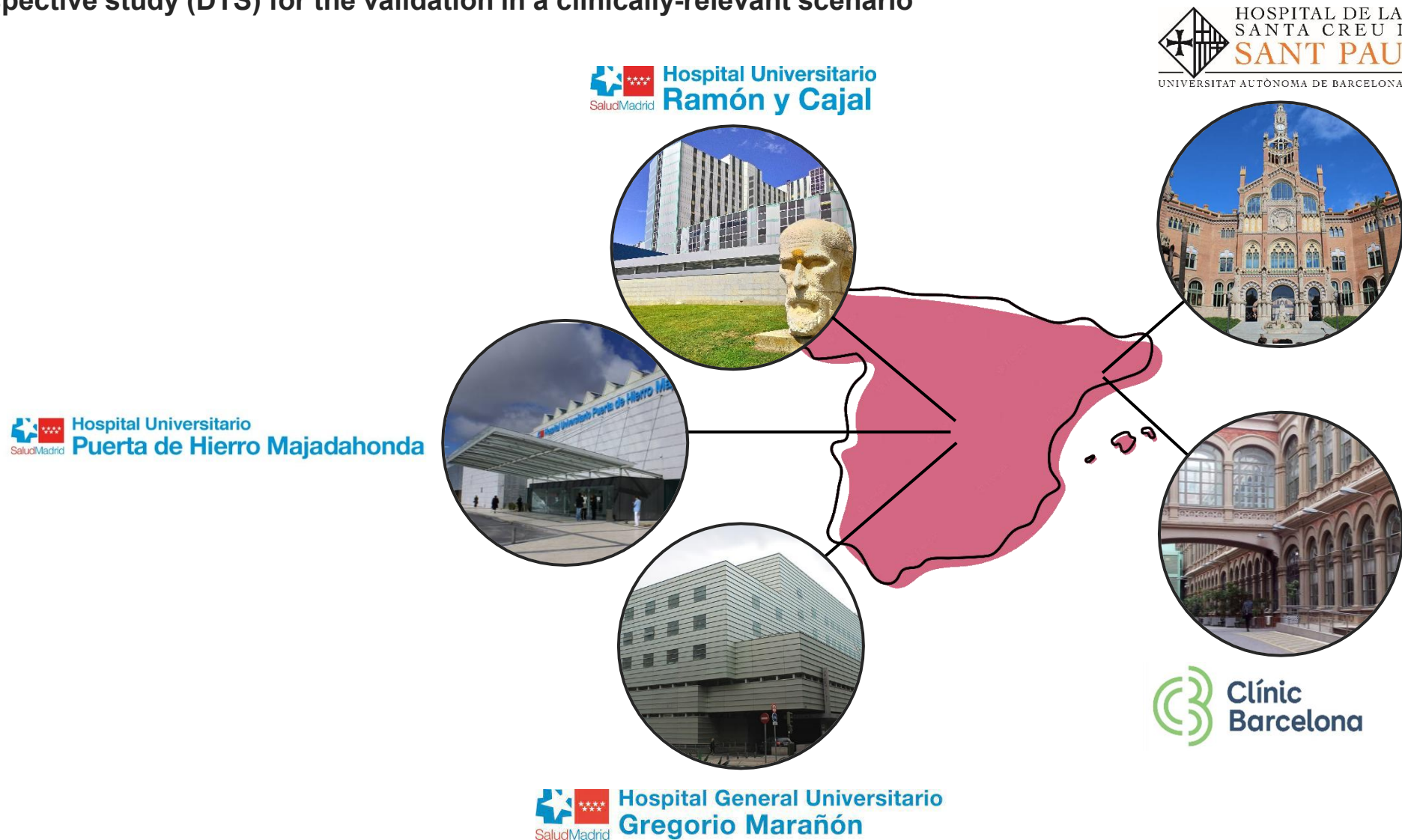
d) Current status of development



2. The Product – PH Care

d) Current status of development

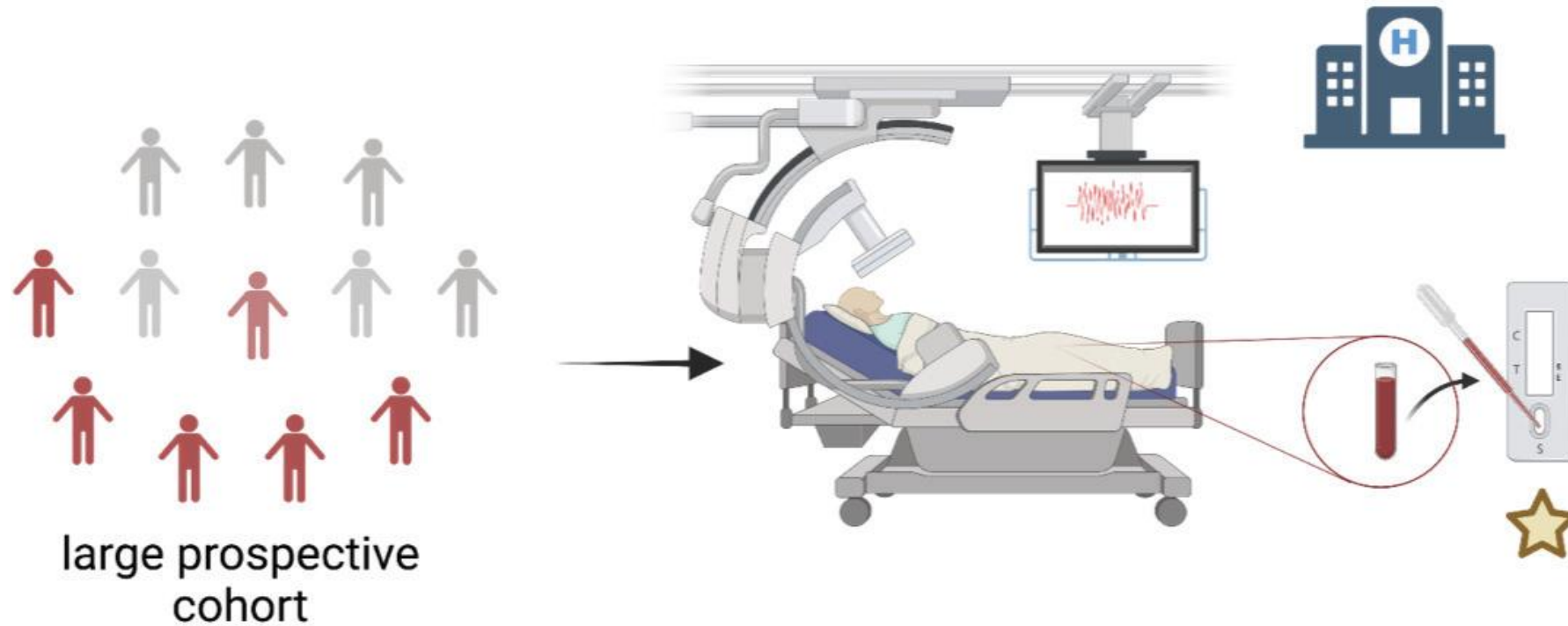
Prospective study (DTS) for the validation in a clinically-relevant scenario



2. The Product – PH Care

d) Current status of development

Prospective study (DTS) for the validation in a clinically-relevant scenario



2. The Product – PH Care

d) Current status of development

We seek for support in the development of the business plan and associated regulatory roadmap

2. The Product – PH Care

e) IPR protection

Patented, PCT phase

2. The Product – PH Care

f) Pitfalls & Risks to be considered

<p>Strengths</p> <ul style="list-style-type: none">• Non-Invasive Approach: avoids invasive procedures like catheterization or endoscopy.• Early Detection Potential: biomarkers may predict portal hypertension early.• Market Differentiation: few reliable non-invasive tools; first-mover advantage.• Clinical Utility: stratifies patients for monitoring and treatment.• Cost-Effective Alternative: reduces costs vs. invasive diagnostics.	<p>Weaknesses</p> <ul style="list-style-type: none">• Biomarker Validation Required: needs extensive clinical validation.• Regulatory Hurdles: stringent approval processes (e.g., FDA, CE).• Dependency on Sample Quality: handling variability may affect accuracy.
<p>Opportunities</p> <ul style="list-style-type: none">• Growing Demand: preference for blood-based tests in hepatology.• Personalized Medicine: fits precision medicine for liver disease.• Integration with Care Pathways: complements imaging and lab tests.• Pharma & Biotech Partnerships: potential companion diagnostic.	<p>Threats</p> <ul style="list-style-type: none">• Competition from Imaging: techniques like FibroScan gaining traction.• Regulatory Delays: may hinder market entry and investor confidence.• Reimbursement Challenges: insurance coverage can be complex and slow.

3. Partnering Opportunities

We seek for IVD investors who would like to incorporate our kit in their portfolio and/or who are willing to support us through the development.

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