



Ability Pharma

real medicine for real life

INTERACTIONS WITH EUROPEAN MEDICINE AGENCY

EIC EMA EVENT

JANUARY 2023





Who we are?

Leading the way in autophagy

ABTL0812 a pioneering approach to cancer treatment

Innovative Mechanism of Action

ABTL0812 selectively kills cancer cells through AUTOPHAGY

Triple Antitumor Effect

- AUTOPHAGY
- SYNERGY with CT
- Turns tumors from COLD to HOT immunogenic

Positive Phase 2a Results

ENDOMETRIAL & LUNG CANCER
 ORR ↑ PFS ↑ OS ↑
 Lung: 11,2 mo → 22,3 mo
 SPAIN - FRANCE

Phase 2b Ongoing

PANCREATIC CANCER (PDAC)
 Double-blind placebo-controlled
 USA – FRANCE - SPAIN
 ISRAEL

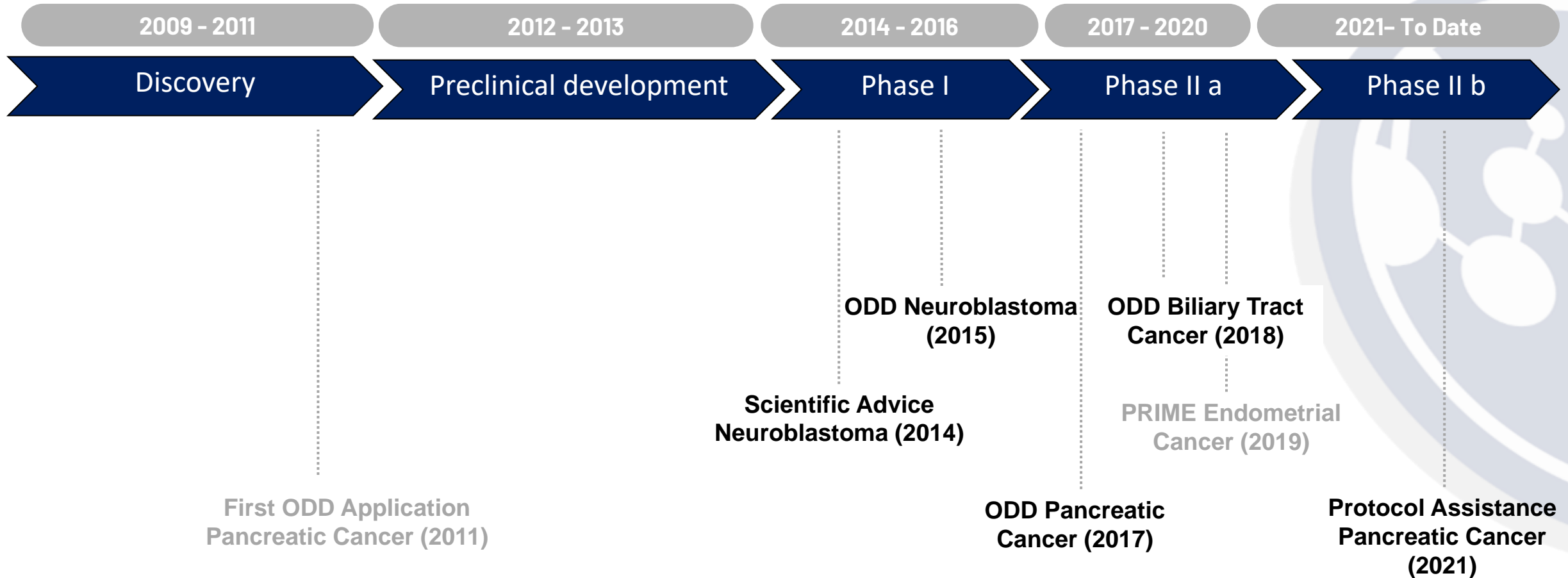
Broad IP portfolio

NEW CHEMICAL ENTITY
 Chemical synthesis
 ORAL SOLUTION
 CAPSULES



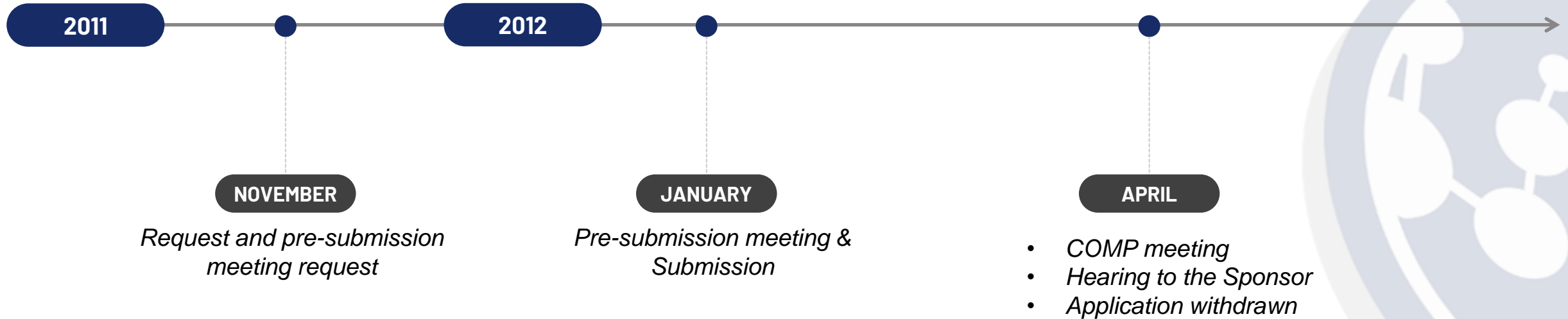
- 👉 EMA SME status granted in 2012, with yearly renewals
- 👉 Orphan drug designation (ODD) for pancreatic cancer, biliary cancer and neuroblastoma
- 👉 EIC Accelerator pilot grant (H2020) blended financing first applied in Jan 2020, granted in March 2020 (5.2 M €). Grant # 954825 - PanC-ASAP

Historical Development Timeline



Our interactions with the EMA – ODD example

2011: ODD pancreatic cancer request - WITHDRAWN



Feedback provided:
Significant benefit data limited
APPLICATION WITHDRAWN

Our interactions with the EMA – **ODD example**

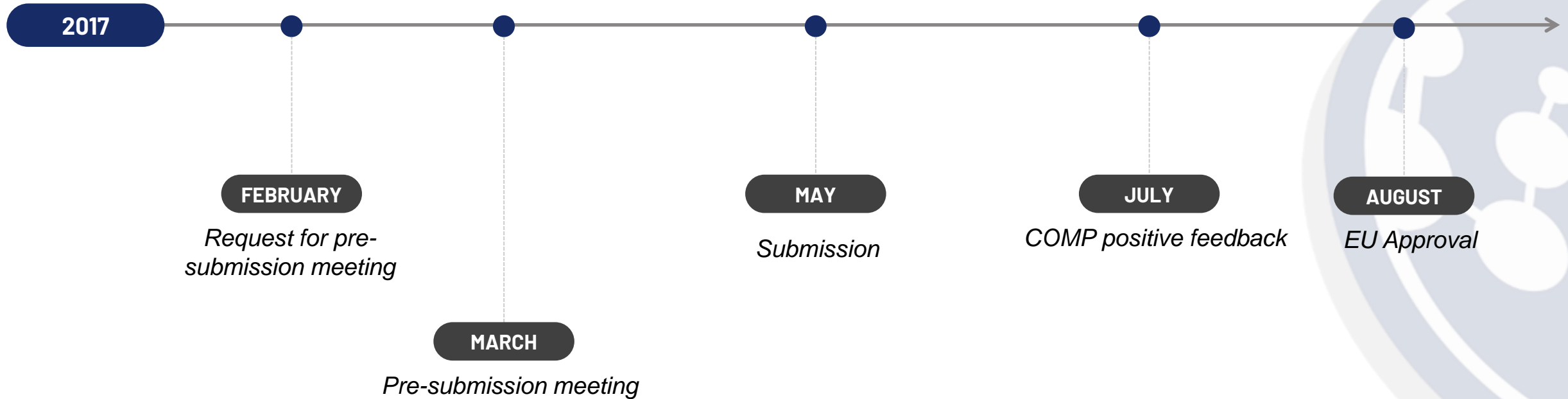
2012: ODD pancreatic cancer request Lessons learned

- ✓ Pre-submission meetings are useful to identify the submission weaknesses, BUT NO WARRANT OF SUCCESS
- ✓ Prepare detailed list of questions
- ✓ Meeting with EMA officers & Committee members permit high quality interactions
- ✓ Instructions to re-apply: Demonstration of SIGNIFICANT BENEFIT IS KEY to succeed if other treatments are available.
- ✓ FDA does not have significant benefit requirements



Our interactions with the EMA – ODD example

2017: New ODD pancreatic cancer request - APPROVED



Tips for ODD maintenance:

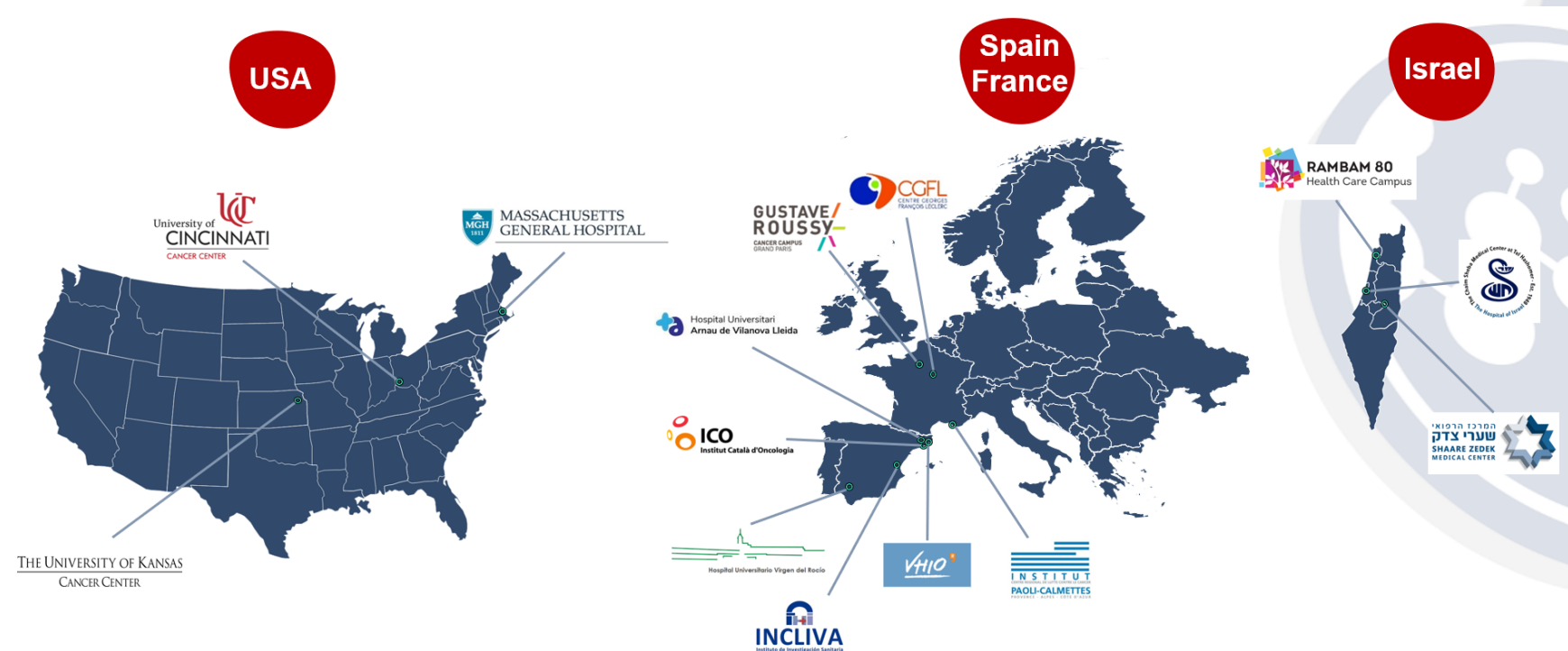
Be aware that yearly renewals are required – annual report
Verify and test IT requirements for submission in advance



ABTL0812 phase 2b trial ongoing

To assess safety and efficacy in Metastatic Pancreatic Cancer (PDAC)

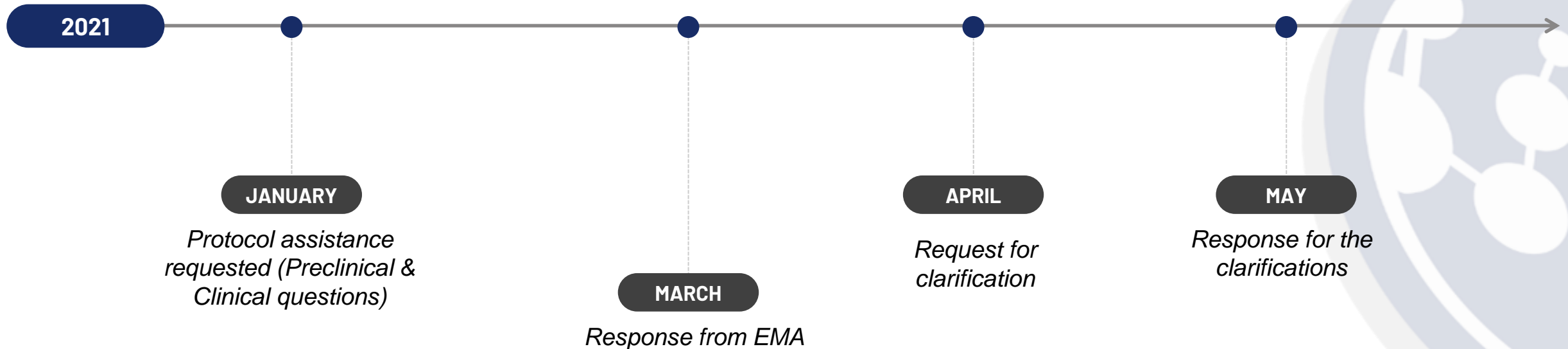
Double blind, Placebo-controlled, Randomized, multicenter Dose-escalation Study of ABTL0812 administered Orally as a Combination Agent with SoC to Subjects with Metastatic Pancreatic Cancer EUDRA CT 2020-002791-13



> The trial could be transformed into phase 3 pivotal trial leading to an early approval expected in 2025

Our interactions with the EMA – Protocol assistance

Ability Pharmaceutical applied (January) for an EIC accelerator pilot grant for the development of ABTL0812 in pancreatic cancer (PanC-ASAP) - Granted in March 2020.



 **Feedback provided:**
All interactions were in writing
Lack of opportunities for dialog through F2F meetings or video-conference

Our interactions with the EMA – **Protocol assistance**

2021: Protocol Assistance Lessons learned

- ✓ Feedback received permits to re-design the protocol to meet requirements for an accelerated approval
- ✓ Clear questions – Clear answers
- ✓ Always try to have a meeting (video-conference or face-to-face): Personal interactions allow to clearly present company positions and to clarify if needed





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Thank you!

www.abilitypharma.com

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