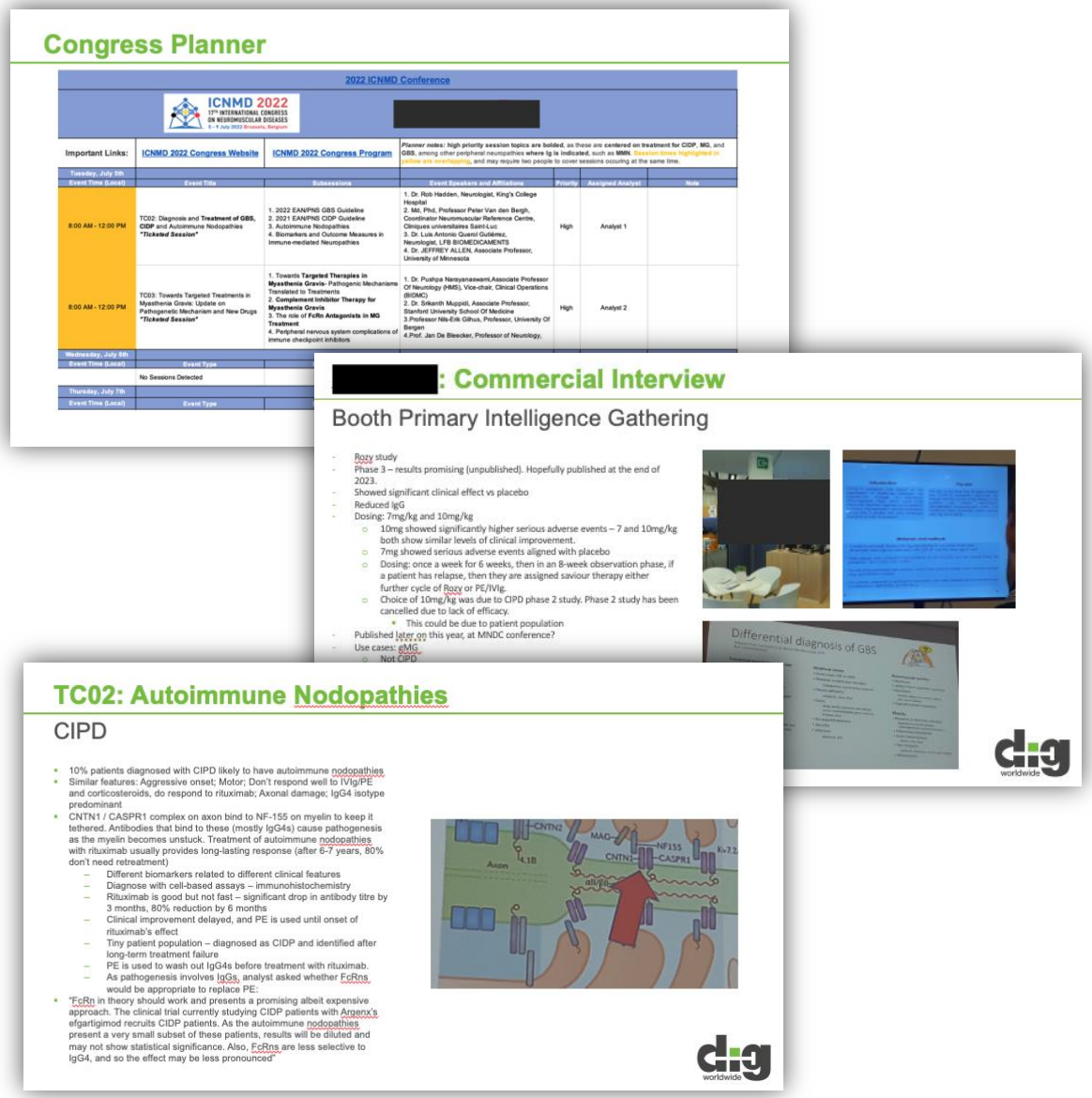
Congress

Intelligence gathering all in one place

Usually takes place over 3-5 days

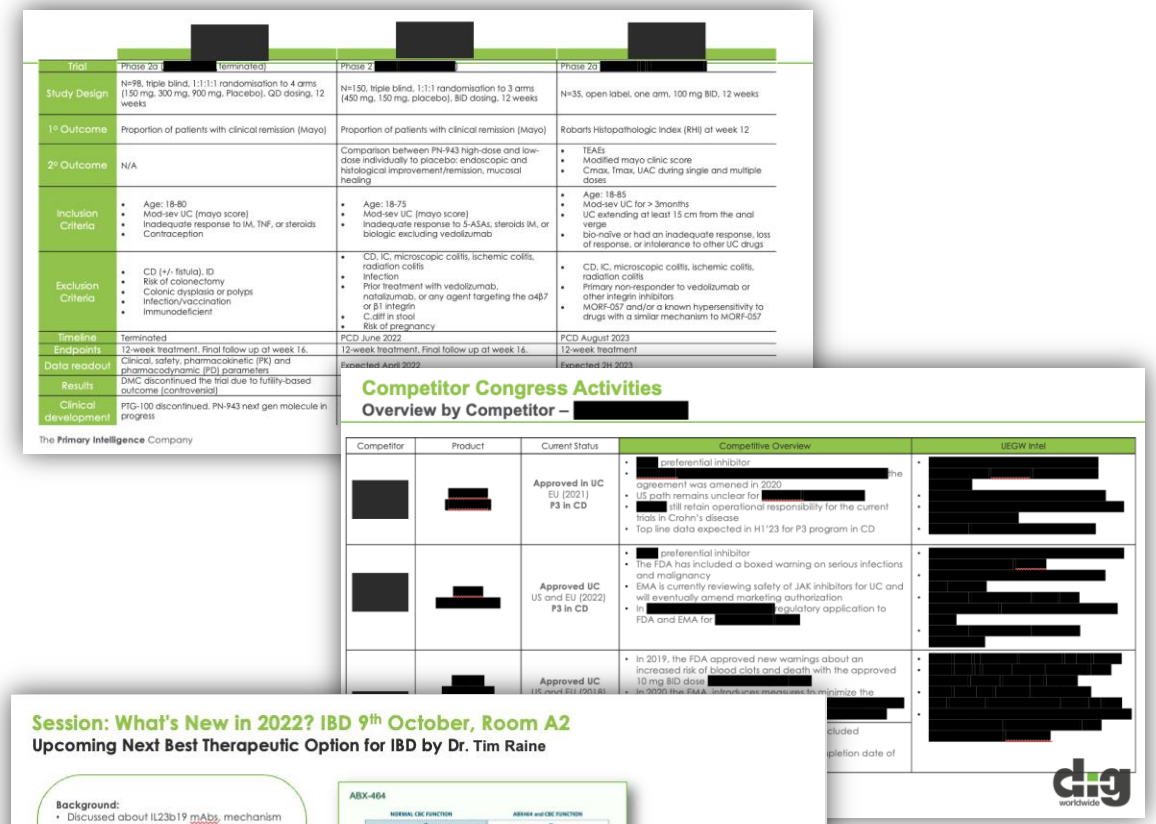
Case Study: Neuroimmunology Congress Coverage



What	Our client was unable to attend a congress and commissioned Dig Worldwide to attend and conduct primary intelligence for existing and emerging treatment paradigms for three therapy areas. Daily summaries were provided to the client, as well as a mid- and post- congress call to share key insights.
Why	Our client required European coverage of the ICNMD Congress as they were unable to attend themselves. A list of key intelligence questions formed part of a long-term monitoring project for the client and required on-the-ground primary intelligence engaging with KOLs and commercial sources.
Where	EU
How	A Dig analyst attended the ICNMD Congress in Brussels to attend high priority sessions; identify clinical and commercial KOLs through networking and research answers to a list of key intelligence questions.

dig worldwide

Case Study: Immunology Congress Coverage



Trial	Phase 2b [redacted] Terminated	Phase 2 [redacted]	Phase 2a [redacted]
Study Design	N=98, triple blind, 1:1:1:1 randomisation to 4 arms (150 mg, 300 mg, 900 mg, Placebo), QD dosing, 12 weeks	N=150, triple blind, 1:1:1 randomisation to 3 arms (450 mg, 150 mg, placebo), BID dosing, 12 weeks	N=35, open label, one arm, 100 mg BID, 12 weeks
1º Outcome	Proportion of patients with clinical remission (Mayo)	Proportion of patients with clinical remission (Mayo)	Roberts Histopathologic Index (RHI) at week 12
2º Outcome	N/A	Comparison between PN-943 high-dose and low-dose individually to placebo: endoscopic and histological improvement/remission, mucosal healing	• TEAEs • Modified mayo clinic score • Cmax, Tmax, UAC during single and multiple doses
Inclusion Criteria	• Age: 18-80 • Mod-sev UC (mayo score) • Inadequate response to IM, TNF, or steroids • Contraception	• Age: 18-75 • Mod-sev UC (mayo score) • Inadequate response to 5-ASAs, steroids IM, or biologic excluding vedolizumab	• Age: 18-85 • Mod-sev UC for > 3months • UC extending at least 15 cm from the anal verge • bio-naïve or had an inadequate response, loss of response, or intolerance to other UC drugs
Exclusion Criteria	• CD (+/- fistula), ID • Risk of colonectomy • Colonic dysplasia or polyps • Infection/vaccination • Immunodeficient	• CD, IC, microscopic colitis, ischemic colitis, radiation colitis • Infection • Prior treatment with vedolizumab, natalizumab, or any agent targeting the α4β7 or β1 integrin • C.diff in stool • Risk of pregnancy	• CD, IC, microscopic colitis, ischemic colitis, radiation colitis • Primary non-responder to vedolizumab or other integrin inhibitors • MORF-057 and/or a known hypersensitivity to drugs with a similar mechanism to MORF-057
Timeline	Terminated	PCD June 2022	PCD August 2023
Endpoints	12-week treatment. Final follow up at week 16.	12-week treatment. Final follow up at week 16.	12-week treatment
Data readout	Clinical, safety, pharmacokinetic (PK) and pharmacodynamic (PD) parameters		
Results	DMC discontinued the trial due to futility-based outcome (controversial)		
Clinical development	PTG-100 discontinued. PN-943 next gen molecule in progress		

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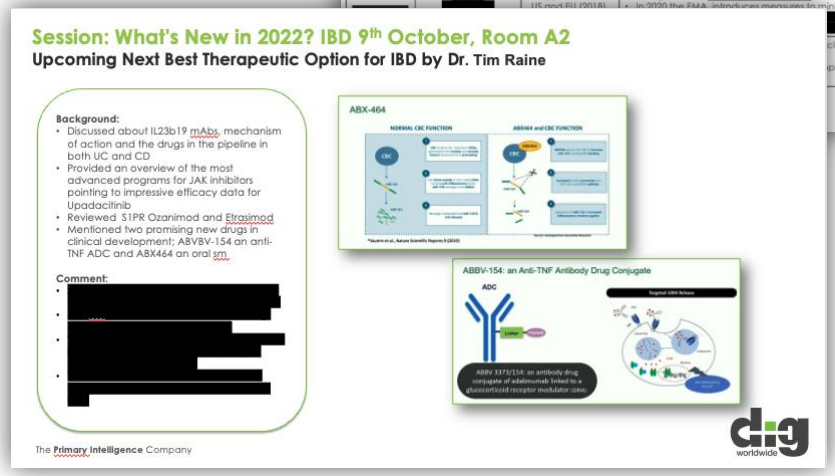
Competitor Congress Activities

Overview by Competitor – [redacted]

Competitor	Product	Current Status	Competitive Overview	UEGW Intel
[redacted]	[redacted]	**Approved in UC** EU (2021) **P3 in CD**	• [redacted] preferential inhibitor • [redacted] the agreement was amened in 2020 • US path remains unclear for [redacted] • [redacted] still retain operational responsibility for the current trials in Crohn's disease • Top line data expected in H1'23 for P3 program in CD	• [redacted]
[redacted]	[redacted]	**Approved UC** US and EU (2022) **P3 in CD**	• [redacted] preferential inhibitor • The FDA has included a boxed warning on serious infections and malignancy • EMA is currently reviewing safety of JAK inhibitors for UC and will eventually amend marketing authorization • In [redacted] regulatory application to FDA and EMA for [redacted]	• [redacted]
[redacted]	[redacted]	**Approved UC** US and EU (2018)	• In 2019, the FDA approved new warnings about an increased risk of blood clots and death with the approved 10 mg BID dose [redacted] • In 2020 the EMA introduces measures to minimize the [redacted] [redacted] cluded [redacted] pletion date of	• [redacted]



Session: What's New in 2022? IBD 9th October, Room A2

Upcoming Next Best Therapeutic Option for IBD by Dr. Tim Raine

Background:
- Discussed about IL23b19 mAbs, mechanism of action and the drugs in the pipeline in both UC and CD
- Provided an overview of the most advanced programs for JAK inhibitors pointing to impressive efficacy data for Upadacitinib
- Reviewed S1PR Ozanimod and Etrasimod
- Mentioned two promising new drugs in clinical development; ABVBV-154 an anti-TNF ADC and ABX464 an oral sm

Comment:
- [redacted]

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What	Dig Worldwide attended an immunology congress in Europe on behalf of our client as part of an ongoing monitoring project. Dig generated an in-depth report on the congress sessions, including key research data, and an analysis of how this impacts our client's relevant therapy area.
Why	Our client owned early pipeline immunology assets and required a competitor landscape, running from actual to ten years out, focusing on new entrants that would compete with their asset. Our client was also looking to understand the value of the assets as it prepared for an acquisition.
Where	EU
How	Dig analysts attended the congress to conduct clinical and commercial primary intelligence focused on a list of key intelligence questions from KOLs. Each congress session was attended, and a report was delivered to the client.