Clinical Debriefs
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Problem: What is the best location to conduct a Phase 1 clinical study for a wakefulness/sleep-related drug?

Summary:

Phase 1 SAD/MAD: Australia is still currently the best for Phase 1 SAD/MAD as fast, cheap, good healthy volunteer centres

Phase 1b PD can consider Czech Republic/ Canada - Poland and CR similar price to Aus, Canada and UK slightly more expensive but better credibility. Canada has more operational speed than UK

Phase 2: UK/ USA: Pick large sleep sites for mechanistic studies, niche populations

Phase 3 - USA, Japan, EU, Aus - Global sites to aid recruitment

Locations reviewed:

Location	Advantages	Disadvantages
Australia	1. Cheap with tax rebates 43% 2. Fast starts 3. Strong healthy volunteer units will be good for adaptive SAD/MAD 4. XW10172 being developed in Aus for narcolepsy - Phase 1 SAD done 5. BIIB080 and Gantenerumab CNS Alzheimers Drug Phase 2 in Aus	1. Smaller population for niche narcolepsy recruitment for follow on Phase 2 2. Sleep lab endpoints may be restricted to certain sites
Canada	1. Good sleep centres - good recruitment for healthy volunteers 2. Lower cost than US - some rebates and tax incentives. CAD cheaper 3. FDA-relevant regulatory pathway - slightly easier to get into USA if ICH-GCP compliant 4. Quick recruitment for Phase 1 from cities 5. Examples of CROs: Altasciences, Biopharma Services, Syneos, IQVIA, ICON	1. Rare sleep conditions less ideal than USA but better than Aus - slower recruitment for phase 2 2. Site sleep capability variable 3. Less KOL density than USA 4. Fewer rebates than Aus

	6. Eg of CNS drugs developed: Astellas Pharma, Arena Pharma did Phase 2 in Canada	
UK	1. Strong academic sleep/neuro centres that will be good for mechanistic studies and biomarkers 2. Still 30-40% cheaper than USA (Phase 1 $2-6M) 3. NT local knowhow to help this along 4. SB-649868 from GSK did Phase 1 in Surrey 5. ADZ4041 AZ CNS drugs developed here 6. Potential CROs a. hVIVO - best for sleep and startups b. ICON c. Parexel - best for FDA strategy d. Labcorp e. WorldWide clinical trials f. MAC - Budget option	1. Recruitment fast but site contracting can be slower due to NHS complexity 2. More expensive than Aus/ Poland but less than USA - comparable to Canada
Netherlands/ Germany	1. Strong sleep medicine and CNS pharmacology 2. High data quality 3. Good EU credibility 4. Strong Sleep precedence: a. Daridorexant b. Suvorexant c. TAK-925 5. Netherlands > UK > Germany 6. Potential NE centres: a. CHDR b. QPS netherlands 7. Potential German CRO a. FutureMeds b. FGK Clinical Research	1. Language barrier 2. Not as cheap as Aus and potentially slower too
Japan	1. Strong sleep-drug ecosystem 2. Orexin precedent	1. Language and cultural barrier

	3. High quality studies	2. Expensive and operationally complex - cost similar to USA 3. Use if Asia/Japan market or orexin-specific KOL input matters
South Korea	1. Dense urban recruitment 2. High-quality hospitals; 3. Cheaper than USA 4. Decent sleep infrastructure	1. Used more in Phase 3 sleep trials 2. No Sleep precedent yet from here
USA	1. Best FDA credibility for final commercial approval 2. Deep sleep centres 3. Easy KOL engagement 4. Largest patient pools for narcolepsy/OSA/insomnia 5. Solriamfetol and Suvorexant had Phase 1 in USA	1. COST +++ 2. Worth considering for Phase 2 and 3 and clinical POC if USA FDA path important commercially
Poland	1. One of the most established Central/Eastern Europe (CEE) clinical hubs - Warsaw and Krakow good 2. Large healthy volunteer pools 3. Best cost for EU = similar to Australia 4. Good recruitment speed 5. Increasingly being used by biotechs in EU 6. Good English 7. Examples of CROs: a. ClinPharm b. CROS c. Chromos d. ICON e. Parexel	1. Quality variability between sites 2. More sponsor oversight required vs UK/Australia 3. Slower regulatory timelines and contracting 4. Smaller specialized sleep-lab ecosystem versus UK/US - need to vet sites better
Czech Republic	1. High-quality CNS PIs, centres and data quality - better than Poland 2. Experienced Phase 1 units in Prague 3. Similar cost to Aus 4. Strong regulatory credibility in EU, UK, USA	1. Smaller population to Poland so recruitment can be a bit constrained 2. Slightly more expensive than Poland

	5. CRO examples: a. PSI b. Cromos c. IQVIA d. ICON e. Parexel f. PPD	
Hungary	1. Cheaper than CR above 2. Good for CNS studies 3. Historically very good clinical trials market 4. Fast enrollment, lower cost than Poland - good centre economics 5. Excellent PI 6. Example CROs: a. Synexus b. Cromos c. PSI d. Medpace e. WorldWide Clinical Trials f. Syneos Health	7. Some political instability 8. Variable English 9. Fewer globally recognised sleep centres

Open Uncertainties

1. Interview all Aus CROs based on Criteria
2. Estimate costs and timings
3. Pick Aus CRO based on this
4. Finalise Phase 1 protocol