



Hatchtech Phase 2a Clinical Trial Case Study

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Hatchtech Pty Ltd

- Founded by Dr Vern Bowles, The University of Melbourne, 2001
- Developing novel products for the control of pests/parasites
- Lead product:
 - DeOvo™ - single application topical treatment for control of head lice (Phase 2)
- Investors: Uniseed, GBS Venture Partners, Founder, Biocomm, Queensland Investment Corporation, Westscheme, The University of Melbourne Endowment Trust and One Ventures.

Lead Product: DeOvo™

- New paradigm for head lice treatment
- Single 10 minute application
- Targets all stages of lice lifecycle including eggs
- Novel agent and mode of action
- Proprietary product with patent protection
- Stage of Development: Phase 2

Phase 2a Clinical Trial dictated by FDA

- Objective: Safety and Tolerability following single application of DeOvo™
(Also investigate pharmacokinetics of Ha44 and assess ovicidal and lousicidal activity)
- Subjects: 30 adults with minimum 5 live lice and 5 viable eggs
- Design: Double blind, randomised and placebo (vehicle) controlled
- Dose: Single dose of -
 - 0.37% DeOvo™ 10 minutes (10 subjects)
 - 0.74% DeOvo™ 20 minutes (10 subjects)
 - Placebo/Vehicle 10 or 20 minutes (10 subjects)

Factors influencing the Choice of Site

1. Recruitment potential
 2. Experience
 3. Ability to work with team
 4. Cost
- Possible Site(s)
 - US
 - Australia
 - India
 - India (Drug Monitoring Research Institute) was selected based on the assessment criteria listed above and successful feasibility assessment

Factors influencing the Choice of CRO

1. Ability to interface with the study site and Hatchtech
 2. Experience of key team members
 3. Full service offering
 4. Cost
- Trident Clinical Research was chosen:
 - Australian CRO with Office based in India
 - Dedicated experienced Indian based Project Managers
 - Strong data management capability (Australia)

Regulatory and IRB Approvals

- Key issues faced:
 - Regulatory Approval time protracted
 - The 'fast track system' failed, significant delays
 - IRB approval process straight forward

Study Conduct

- Initiation
- Recruitment
- Time to completion
- Data transfer and management straight forward
- Labs, bioanalytical, surrogate marker testing
- Protocol deviations

Control and Monitoring

- Largely overseen by CRO
 - Strong PM
 - Regular monitoring
- CSO on site for key initial set-up, ensuring success with activity measures
- Good communication channels ensured prompt follow up on all queries and issues.

Summary

- Working with Indian Clinical Trial Site was very positive experience