



DiseaseINFOPACK: *Clostridium difficile*

Proposal No/#PO	:	[Enter client specific #PO]
Product Name	:	Comprehensive review/analysis of <i>Clostridium difficile</i> associated disease (DiseaseINFOPACK)
Project Initiation Date	:	n/a
Billable days	:	n/a
Initiator(s)	:	[Enter client name, function and address]
Therapeutic Area	:	<i>Clostridium difficile</i> /antibiotics
Product (if applicable)	:	CAT No: VADIP001, published November 2009

Background

Clostridium difficile (C.diff) is a Gram-positive bacterium, which in vulnerable hospitalized patients can cause gastrointestinal infections (CDAD/CDI). Outcomes range from mild uncomplicated diarrhea to severe-complicated disease where patients experience fever, tachycardia and pseudomembranous colitis. Risk factors for C.diff infections are >65 yrs of age, hospitalization, severe underlying illness coupled with chronic antibiotic therapy.

Although CDAD can be managed usually by stopping antibiotic therapy or the use of metronidazole and vancomycin treatment, patient mortality can still reach 6-30%¹. In some patients with toxic megacolon who require surgical intervention or colectomy, mortality can reach even higher rates of 35-50%. In the UK, C.diff is estimated to have been a factor in the death of over 3000 people in 2005 (ONS Figures) with numbers often exceeding MRSA related deaths. *Clostridium difficile* can also cause hospital outbreaks associated with ward closures and high economic cost.

In the US, the Centers for Disease Control and Prevention (CDC) estimates that 400-500,000 cases of CDAD occurred in 2004 where incidence is estimated at 10-200 cases per 10,000 admissions². More significantly, previous research conducted by **VacZine Analytics**³ with international opinion leaders indicates that they believe the incidence of CDAD is increasingly year-on-year in their countries. This dynamic coupled with increasing disease severity and a lack of newer treatments has prompted the search for newer antibiotics and biologic based strategies including prophylactic vaccines/passive monoclonals.

¹ Bartlett JG et al. Clinical Practice. Antibiotic-associated diarrhea. N Engl J Med 2002; 31; 346: 334-9

² US Centers For Disease Control and Prevention (CDC). Available at: http://www.cdc.gov/ncidod/dhqp/id_cdifff.html. Accessed July: 2008.

³ **VacZine Analytics**. *Clostridium difficile*. DiseaseINFOPACK (CAT No: VADIP001) and OpportunitySCAN (CAT No: VAOPS001), previously published August 2008

PRODUCT CONTENTS:**Published/updated November 2008.**

- SECTION 1:** The pathogen and associated disease
- SECTION 2:** Treatment overview
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Disease trends and dynamics
Increasing severity
Reasons for increased severity
Key issues and challenges
Establishing key unmet needs in CDAD
Current R&D pipeline – CDAD treatments
Expert viewpoints: emerging treatments
A C.diff vaccine is currently in development^
Overall vaccination strategy: prophylactic
Appendix I – Bibliography
Appendix II – About VacZine Analytics

*Other EU countries available upon request

^ For an in depth analysis of the C.diff active vaccine opportunity please refer to products CAT No: VAOPS001 and VAMV001

PAGES: >100 powerpoint slides, fully referenced/sourced

PROJECT METHODOLOGY:

VacZine Analytics has conducted a comprehensive secondary research to review all available information regarding CDAD/CDI in major EU/Canada and US markets. Source materials used are literature articles, government websites, medical bodies and associations, conference proceedings etc. Published research from **VacZine Analytics** has also been utilised.

International global opinion leaders/experts in CDI were interviewed as part of this research.

PRODUCT COST:

VacZine Analytics will grant a [enter region] license to [enter client name], USA for the price of:

- \$8295.00 (US license)

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TERMS and CONDITIONS:

VacZine Analytics – a trading division of Assay Advantage Ltd UK Company Number: 5807728 (Herein referred to as “The Company”). (Herein [enter client name] to as “The Client”).

1. The service provided is described in the proposal document. Any additional service required by the client will be subject to a new proposal being prepared.
2. Work on any project will commence after written (e-mail) or Fax confirmation stating the Client’s acceptance of the last proposal according to the program proposed by the Client.
3. Acceptance of the last proposal is deemed to include acceptance by the Client of these terms of business, which shall not be varied except by express agreement signed by the Company and the Client.
4. If at any time, the Client requests that the project brief, the project materials, the timings or method are changed in any way or the commencement of the study delayed, the Company reserves the right to revise the proposal and/or the resultant timings.
5. Invoicing will **100%** after submission of deliverables to the Client in a form reasonably acceptable to the Client.
6. All invoices are payable within **thirty days** of the invoice date.
7. All proposals are quoted in **\$USD dollars** and invoices are to be settled in the same currency.
8. Reasonable travel and incidental costs that are pre-agreed with the Client and incurred by The Company, whether to present findings to the Client at a determined location or to conduct project related activities will be added to the final invoice.
9. If the project is shortened, cancelled or otherwise terminated by arrangements between the Client and the Company, the Company shall be reimbursed for all previously authorised expenditure plus 10% unless such termination is due to failure to perform or breach of this agreement by the company
10. The Company agrees not to disclose to any third party confidential information acquired in the course of providing the services listed without the prior written consent of the Client. Exception occurs when the information is already in the public domain or when disclosure is necessary to help the Company’s employees and agents with the performance of the Company’s obligations to achieve satisfactory completion of the project and approved in writing by the Client.
11. Force Majeure: The Company will not be liable for any delay or failure to perform any obligation under this Agreement insofar as the performance of such obligation is prevented by an event beyond our reasonable control, included by not limited to, earthquake, fire, flood or any other natural disaster, labour dispute, riot, revolution, terrorism, acts of restraint of government or regulatory authorities, failure of computer equipment and failure or delay of sources from which data is obtained.

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About VacZine Analytics:

VacZine Analytics is a new strategic research agency based in the United Kingdom. Its aim is to provide disease and commercial analysis for the vaccine industry and help build the case for developing new vaccines and biologics

For more information please visit our website www.vacZine-analytics.com

Dr John Savopoulos

VacZine Analytics is led by John Savopoulos.

John has worked in the healthcare industry for more than 10 years both in research and development, new product evaluation and strategic marketing. He has spent time at GlaxoSmithKline and Novartis Vaccines (formerly Chiron Vaccines) where in the latter he was Director, New Product Evaluation and Marketing.

John was also Head of Infectious and Respiratory Diseases at Datamonitor Healthcare PLC where he led a team of analysts whose work was widely published in the financial and academic press. He also appeared on BBC's The Money Program, 2005 – "The irresistible rise of Tony's Crony" as a vaccine industry analyst.

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