

\*\*\*\*Updated January 2014\*\*\*\*

## MarketVIEW: *Clostridium difficile* vaccines (CAT: VAMV001)

<b>Product Name</b>	:	<b>MarketVIEW: <i>Clostridium difficile</i> vaccines</b>
<b>Description</b>	:	Global vaccine commercial opportunity assessment
<b>Contents</b>	:	Executive presentation + 1 forecast models
<b>Therapeutic Area</b>	:	Novel nosocomial vaccines
<b>Publication date</b>	:	January 2014
<b>Catalogue No</b>	:	VAMV001

## Background

*Clostridium difficile* (*C.diff*) is a Gram-positive bacterium, which in vulnerable hospitalized patients can cause gastrointestinal infections (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%<sup>1</sup>. In some patients with toxic megacolon who require surgical intervention or colectomy, mortality can reach even higher rates of 35-50%.

This **MarketVIEW**<sup>2</sup> product is a comprehensive commercial opportunity assessment which forecasts the potential of C.DIFF vaccines to 2030 in the major Western markets. All potential vaccine indications are modelled: with a focus on key target populations as defined by the enrolment criteria of the Sanofi phase 3 CDIFFENSE trial. Also included is an in-depth epidemiology forecast to 2030 including number of CDI cases per country drawing upon latest surveillance data (pan-European survey). A discussion of the potential cost effectiveness implications of the vaccine is included along with an up-to-date review of competitor programs and preclinical activity.

---

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

<sup>2</sup> This product supercedes the previous **VacZine Analytics** publication **MarketVIEW: Clostridium difficile** (CAT No:VAMV001), published March 2013

## Methodology

**VacZine Analytics** has closely monitored all significant source material pertaining to Clostridium difficile disease epidemiology/vaccines. Example, secondary source materials used are literature articles, government websites/databases, medical bodies and associations, conference proceedings and previously analyses (where publically available). Previously published research by **VacZine Analytics** in field of pediatric/endemic vaccines has also been utilised. **\*\*\*See Bibliography for exact sources.**

### PRODUCT CONTENTS:

**Published January 2014 (CAT No: VAMV001)**

\*\*\*\*This product is composed of one model and an Executive presentation

#### Contents – Executive presentation (MS PowerPoint based)

Authors note  
Executive summary  
Model forecast comparisons: January 2014 v March 2013  
Model forecast comparisons: January 2014 v March 2013 (table)  
C.diff vaccines: key model outputs  
C.diff vaccines: global value (\$m), 2015-30  
C.diff vaccines: global volume (doses), 2015-30  
C.diff vaccines: global value, base scenario, 2015-30  
C.diff vaccines: global value, elective admissions, 2015-30  
C.diff vaccines: global value, LTCFs, 2015-30  
Comments on latest C.diff epidemiology  
Epidemiology forecast: incidence per country 2000-2030  
C.diff vaccines: modelling commercial potential  
C.diff vaccine opportunity: target product profile (TPP)  
The role of a C.diff vaccine  
Key model assumptions: overview  
Vaccine target populations: overview  
Vaccine target populations: Venn diagram  
Vaccine target populations: Market sizing US, 2025  
Pricing  
Overview of modelling strategy: elective admissions  
Target populations: US and England elective procedures  
Target populations: Long-term care facilities  
Target populations: “at risk” 65yrs+  
Coverage rates (at least one dose, at least three doses)  
Competitor landscape: overview  
C.diff vaccines: research and development pipeline  
Sanofi Pasteur: toxoid vaccine  
Pfizer vaccines  
Valneva  
Preclinical programs  
Epidemiology: situation overview  
Acute care hospitals: US  
Acute care hospitals: England  
Acute care hospitals: Germany  
Acute care hospitals: pan-European

Bibliography  
Disclaimer  
About VacZine Analytics

**PAGES: ~65 MS PowerPoint slides, fully referenced/sourced. Available in .pdf form**

### **Contents – Vaccine demand model(s) (MS Excel-based)**

Title sheet.  
Charts-by target population.  
Charts-by vaccine.  
Vol Val by country  
Vol Val Sanofi  
Vol Val by 2<sup>nd</sup> entrant  
Elective admissions 50 yrs +  
USA  
Canada  
UK  
France  
Germany  
Italy  
Spain  
Other EU  
Australia  
Universal vaccination 65 yrs +  
USA  
Canada  
UK  
France  
Germany  
Italy  
Spain  
Other EU  
Australia  
At risk 65 yrs +  
USA  
Canada  
UK  
France  
Germany  
Italy  
Spain  
Other EU  
Australia  
Long-term-care facilities (LTCF)  
USA  
Canada  
UK  
France  
Germany  
Italy  
Spain  
Other EU  
Australia  
Existing CDI  
USA



## Continued...

- Canada
- UK
- France
- Germany
- Italy
- Spain
- Other EU
- Australia
- Sources
- Global price summary
- Population database.
- Hospital database.
- Hospital procedures (US)
- Hospital procedures (England)
- CDI cases (all ages)
- US CDI epidemiology
- UK CDI epidemiology
- UK CDI by specialty
- Germany CDI epidemiology
- EU source data.

**Worksheets = ~75**

## PRODUCT COST:

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

- FULL PRODUCT - USD **\$8995.00**/ GBP **£5555.00**<sup>#</sup> (Region license)\*
- PRESENTATION OR MODEL ONLY - USD **\$4995.00** (Region license)\*

<sup>#</sup> Indicative rate only. Prevailing rate applied to date of transaction.

\*A region is North America, Europe or ROW

For orders in the UK, VAT at 20.0% will be added to final invoice total

## HOW TO ORDER:



To order please contact your region account manager or order direct at [orders@vaczine-analytics.com](mailto:orders@vaczine-analytics.com)  
This report can also be purchased on-line. Please review the **TERMS and CONDITIONS** of purchase.

**VacZine Analytics (R)** is a trading division of Assay Advantage Ltd, UK Company Number: 5807728

**VacZine Analytics (R)** and the “spiral logo” are UK Registered Trademarks, 2009

## BIBLIOGRAPHY:

1. Asensio Á et al. [Cost of Clostridium difficile associated diarrhea in Spain]. Rev Esp Salud Publica. 2013 Jan-Feb;87(1):25-33.
2. McGlone SM et al. The economic burden of Clostridium difficile. Clin Microbiol Infect. 2012 Mar;18(3):282-9.
3. CDI Europe. Clostridium difficile infection in Europe. A CDI Europe Report. April 2013.
4. Lee BY et al. The potential value of Clostridium difficile vaccine: an economic computer simulation model. Vaccine. 2010 Jul 19;28(32):5245-53.
5. Maltenfort MG et al. Clostridium difficile colitis in patients undergoing lower-extremity arthroplasty: rare infection with major impact. Clin Orthop Relat Res. 2013 Oct;471(10):3178-85.
6. Hospital Episode Statistics, Admitted Patient Care, England - 2012-13: Procedures and interventions. Available at: <http://www.hscic.gov.uk>. Accessed: November 2013.
7. Agency for Healthcare Research and Quality. HCUPnet database. Available at: <http://hcupnet.ahrq.gov/>. Accessed: November 2013
8. CalQualityCare.org: Types of Long Term CareTypes of Long Term Care . Available at: [www.chcf.org](http://www.chcf.org). Accessed: December 2013.
9. Residential Care Facilities: A Key Sector in the Spectrum of Long-term Care Providers in the United States. NCHS Data Brief. Number 78, December 2011. Available at: <http://www.cdc.gov/nchs/data/databriefs/db78.htm>. Accessed: December 2013.
10. MDS Active Resident Information Report. Available at: <http://www.cms.hhs.gov>. Accessed: December 2013
11. National Center for Health Statistics. Health, United States, 2012: With Special Feature on Emergency Care. Hyattsville, MD. 2013. Available at: <http://www.cdc.gov/nchs/hsu/contents2010.htm>. Accessed: December 2013.
12. Jones AL et al. The National Nursing Home Survey: 2004 overview. National Center for Health Statistics. Vital Health Stat 13(167). 2009.
13. Jones AL et al. The National Nursing Home Survey: 1999 summary. National Center for Health Statistics. Vital Health Stat 13(152). 2002.
14. Jen MH et al. Assessment of administrative data for evaluating the shifting acquisition of Clostridium difficile infection in England. J Hosp Infect. 2012 Mar;80(3):229-37.
15. 2009 Health and Health Care of the Medicare Population. Available at: [http://cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Data-Tables-Items/2009\\_HHC.html](http://cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Data-Tables-Items/2009_HHC.html). Accessed: December 2013
16. Health Indicators Warehouse. National Center for Health Statistics. Available at: <http://healthindicators.gov/>. Accessed: December 2013.
17. Self-reported pneumococcal vaccination coverage trends 1989 – 2008. Available at: [http://www.cdc.gov/flu/pdf/professionals/nhis89\\_08ppvaxtrendtab.pdf](http://www.cdc.gov/flu/pdf/professionals/nhis89_08ppvaxtrendtab.pdf). Accessed: December 2013
18. Adult Vaccination Coverage — United States, 2010 MMWR February 3, 2012 / 61(04):66-72. Available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6104a2.htm>. Accessed December 2013
19. Clostridium difficile: Are We Making Progress? Ginamarie Foglia, Clinical Director. 28 September 2011, Fondation Merieux, Les Pensières - Annecy (France). Available at: <http://www.globe-network.org>. Accessed: December 2013
20. Sanofi-Aventis. Vaccines IR Seminar. December 17th, 2009. Available at: <http://en.sanofi-aventis.com/>. Accessed: December 2013
21. Zerey M et al. The burden of Clostridium difficile in surgical patients in the United States. Surg Infect (Larchmt). 2007 Dec;8(6):557-66.
22. Greenberg RN et al. Phase I dose finding studies of an adjuvanted Clostridium difficile toxoid vaccine. Vaccine. 2012 Mar 16;30(13):2245-9.
23. Leuzzi R et al. Protective efficacy induced by recombinant Clostridium difficile toxin fragments. Infect Immun. 2013 Aug;81(8):2851-60.
24. Valneva Announces Positive Phase I Results for its Clostridium Difficile Vaccine Candidate. Available at: <http://valneva.com/>. Accessed: December 2013.
25. Stellar Biotechnologies Announces Patents for Clostridium Difficile Immunotherapy Technology Issued in U.S. and China. Available at: <http://www.stellarbiotechnologies.com>. Accessed: December 2013
26. Oral Vaccination against Clostridium difficile Infection. Available at: <http://cdvax.org/>. Accessed: December 2013.
27. Martin CE et al. Glycan arrays containing synthetic Clostridium difficile lipoteichoic acid oligomers as tools toward a carbohydrate vaccine. Chem Commun (Camb). 2013 Aug 18;49(64):7159-61.
28. Seregin SS Adenovirus-based vaccination against Clostridium difficile toxin A allows for rapid humoral immunity and complete protection from toxin A lethal challenge in mice. Vaccine. 2012 Feb 14;30(8):1492-501.
29. National Targets and Metrics. Monitoring Progress Toward Action Plan Goals: A Mid-Term Assessment. Available at: <http://www.hhs.gov>. Accessed: December 2013
30. Hospital Value-Based Purchasing Program – CMS. Available at: [www.cms.gov](http://www.cms.gov). Accessed: December 2013.

31. Health Protection Agency. Quarterly counts of *C. difficile* infection in persons aged 2 years and over (January 2008 - March 2013). Available at: <http://www.hpa.org.uk/>. Accessed: November 2013
32. Health Protection Agency. Quarterly analyses: Mandatory MRSA bacteraemia & *Clostridium difficile* infections (July, 2007 to September, 2009). Available at: <http://www.hpa.org.uk/> on request
33. The Federal Health Monitoring System. Available at: <http://www.gbe-bund.de/>. Accessed: December 2013
34. Burckhardt F et al. *Clostridium difficile* surveillance trends, Saxony, Germany. *Emerg Infect Dis*. 2008 Apr;14(4):691-2.
35. Bauer MP et al. *Clostridium difficile* infection in Europe: a hospital-based survey. *Lancet*. 2011 Jan 1;377(9759):63-73.
36. Barbut F et al. Prospective study of *Clostridium difficile*-associated disease in Europe with phenotypic and genotypic characterization of the isolates. *Clin Microbiol Infect*. 2007;13(11):1048-57

## 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. This finished research product is provided as a Service. Any additional Service required by the client will be subject to a new proposal being prepared.
2. The Service will commence after written (e-mail) or Fax confirmation stating the Client's acceptance of the Service according to the description proposed by the Company.
3. **Cancellation policy.** The Company's cancellation policies are in accordance with the EU Consumer Protection (Distance Selling) Regulations 2000 (DSRs). Prior to acceptance of an order the Company will make available written information regarding Clients cancellation rights. This is posted on the Company website and is available for public review.
4. **Cancellation rights:** For finished documents - a Clients cancellation rights will last for **seven working days** counting from the day that the order was concluded. If the Services i.e. provision of the documents has taken place with the Clients agreement before this period the Client's cancellation rights have ended.
5. Invoicing will **100%** after submission of deliverables to the Client in a form reasonably acceptable to the Client.
6. If not purchased on line invoices are payable within **thirty days** of the invoice date.
7. All proposals are quoted in **\$USD dollars or £GBP** and invoices are to be settled in the same currency.
8. 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.
9. 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.
10. Please also refer to Master **TERMS and CONDITIONS** available upon request.

### VacZine Analytics

Warren House  
Bells Hill  
Bishops Stortford  
Herts  
CM23 2NN  
United Kingdom  
Tel: +44 (0) 1279 654514 / +44 (0) 7952470582 / Fax: +44 (0) 1279 655926  
E-mail: [info@vacZine-analytics.com](mailto:info@vacZine-analytics.com)



## About VacZine Analytics:

**VacZine Analytics** is an established 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](http://www.vacZine-analytics.com)

**VacZine Analytics (R)** is a trading division of Assay Advantage Ltd, UK Company Number: 5807728

**VacZine Analytics (R)** and "the spiral logo" are UK Registered Trademarks, 2009