

參考文獻

中文文獻

1. 工商時報,「CRO 霸主美商昆泰,在台水土不服」,民國九十一年十月十二日。
2. 工商時報,「生技顧問業水漲船高」,民國九十三年十二月廿五日。
3. 王靜波,「全球合同研發外包(CRO)服務業發展動態與趨勢」,上海情報服務平台,2004年十二月。
4. 行政院生物技術產業策略(SRB)會議會議資料,民國九十三年。
5. 李建宏、溫肇東、吳豐祥,「日本生技製藥產業創新模式之研究」,經濟部產業技術資訊服務推廣計畫(ITIS),2004年
6. 秦慶瑤,臨床試驗體系委外產業現況(DCB-0267-S404(90)),生物技術開發中心,民國九十年十二月。
7. 曾政光,「我國 CRO 公司的發展利基與策略」,經濟部產業技術資訊服務推廣計畫(ITIS)報告,2003年。

英文文獻

1. Ann Neuer, Barry Miskin “QA for the Investigative Site: Building the right foundation is critical to success. Here's how to lay the groundwork for excellence.” Applied Clinical Trials, Nov 1, 2004.
2. Applied Clinical Trials, “Education and training directory: A full listing of college and university courses, training classes, and other educational opportunities.” Applied Clinical Trials, Dec 1, 2004.
3. Applied Clinical Trials, “Internet Resources: The following Web sites are focused on the professional and/or potential participant in clinical trials.” Applied Clinical Trials, Dec 1, 2004.
4. CenterWatch, “CRO Market” CenterWatch, Vol.10, Issue 9, Sep, 2003, p.9-11
5. Contract Pharma, “Top 15 CROs For Fiscal 2003”, Contract Pharma, May 2004, p.38
6. Contract Pharma, “Now that Quintiles is going private, what's next?” Contract Pharma Autumn Concerns, Sept 2003, p.28
7. David Cavalla “The extended pharmaceutical enterprise.” Drug Discovery Today, Vol.8(6), March 2003. p.267-274
8. Diana L. Anderson, “The Patient Recruitment Market” Applied Clinical Trials,

Nov 2, 2003.

9. DiMasi JA, Hansen RW, Grabowski HG, “The Price of Innovation: New Estimates of Drug Development Costs.” *Journal of Health Economics*, 2003, Vol 22, p.151–185.
10. DiMasi JA, Hansen RW, Grabowski HG, Lasagna L., “Cost of innovation in the pharmaceutical industry.” *Journal of Health Economics*, 1991, Vol 10, p.107-142
11. Evan Gothard “Understanding Cost Drivers: Lessons Learned from Multiple Perspectives” Quintiles Presentations, 2002
12. Faiz Kermani and Rebecca Gittins, “Finding the Next Asian Pharma Sensation” *Contract Pharma*, May 2004, p.54-59
13. Food and Drug Administration. “CDER 2003 Report to the Nation: Improving Public Health Through Human Drugs”. Rockville, Maryland, 20857. 2004
14. Food and Drug Administration. “Challenge and Opportunity on the Critical Path to New Medical Products.” March 2004.
15. Food and Drug Administration. “FDA Announces Standard Format That Drug Sponsors Can Use to Submit Human Drug Clinical Trial Data.” July 2004.
16. Frost & Sullivan “CRO industry coming under pressure,” (part of F&S’ *Pharmaceuticals Monitor Service*) 2003
17. Graham Hughes, “The CRO Scene in 2003—A Brief Tour.” *European Pharmaceutical Contractor*, Summer 2004, p.8-10
18. Hansen RW, “The pharmaceutical development process: estimate of current development costs and times and the effect of regulatory changes.” 1979, Lexington Books, Lexington, MA, p.151-187.
19. Janice M. Reichert, “Trends in development and approval times for new therapeutics in the united states.” *Drug Discovery*, Sep 2003, Vol 2, p.695-702.
20. Jill Weschler, “Clinical Trial Listings and Results Go Public” *Applied Clinical Trials*, Oct 1, 2004.
21. Kathleen B. Drennan, “Patient recruitment: the costly and growing bottleneck in drug development” *Drug Discovery Today*, February 1 2002, Vol 7, Issue 3, P.167-170.
22. Kenneth A. Getz and John R. Vogel, "Achieving Results with CROs: Their Evolving Role in Clinical Development," *Applied Clinical Trials*, April 1995, 32-38.
23. Mary Jo Lamberti, “Going Global” *Applied Clinical Trials*, Jun 1, 2004
24. Michael A. Martorell, “Consolidation in Outsourcing, A look back at 2003 and a look ahead to 2004,” *Contract Pharma*, Jan 2004.
25. OPPI—Monitor Group Collaboration, “Outsourcing Opportunities in Indian Pharmaceutical Industry.” Sep, 2003.

26. Peter Lissinger, "Outsourcing: Do it Well or Not at All," Drug Discovery & Development, March 2004, Vol.7 Issue 3, P.15
27. Philip J. Holt, James E. Lodge, "Merging Collaboration and Technology: The Virtual Research Organization" Applied Clinical Trials, Oct 1, 2003.
28. Richard A. Retting, "The Industrialization of Clinical Research," Health Affairs 19, no.2 (2000): 129-146
29. Sarah W. Madley, "Snapshot: The CRO Industry Today, Industry strengthens relationships with sponsors, learns the benefits of flexibility and moves more trials out of the developed world." Contract Pharma, May 2004, Vol 6, No. 4, p.40-47
30. Simon Frantz, "Why are clinical costs so high?" Nature reviews drug discovery, Nov 2003, Vol 2, p.851-852
31. Solomon Nwaka and Robert G. Ridley, "Virtual drug discovery and development for neglected diseases through public—private partnerships." Nature Review Drug Discovery, Nov. 2003, Vol 2, p.919-928
32. Steven Heffne, "Beyond The CRO : Other players search for their slice of the drug development pie." Contract Pharma, 2004.03
33. Terumasa Hirai, "Communication between the sponsor and CRO - The contract laboratory perspective" The Quality Assurance Journal, June 1998, Vol 3, Issue 2, P.51-55.
34. The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) , "The Value and Benefits of ICH to Industry" 2000
35. Toby Jane Hindin, "Looking Back, Moving Forward: A CRO Retrospective", Applied Clinical Trials, Aug 2, 2004
36. V.E.K.M. van de Walle "CRO—SMO: Partners in Business or Business Partners?" Monitor, Spring 2002, p.25-28

網頁資料

1. Applied Clinical Trials, <http://www.actmagazine.com/appliedclinicaltrials/>
2. Contract Pharma, <http://www.contractpharma.com/>
3. PhRMA, "Updated Principles For Conduct Of Clinical Trials And Communication Of Clinical Trial Results," <http://www.phrma.org/mediaroom/press/releases/30.06.2004.427.cfm>
4. Quintiles Transnational Corp., Form 10-K (<http://www.quintiles.com>) Dec. 2003
5. R&D Directions Staff, "Prospects are good." <http://www.rddirections.com/magazines/randd/view.cfm?articleID=1279>
6. The U.S. Food and Drug Administration (FDA) website, <http://www.fda.gov>

7. TheStreet.com, "Cashing in on privatization,"
<http://www.thestreet.com/markets/rebeccabyrne/10088838.html>
8. Triangle Business Journal, "In depth: largest triangle deals of 2003,"
<http://www.bizjournals.com/triangle/stories/2004/02/09/focus1.html>
9. Trimanos Corp. website, <http://trimanos.com/resources/stakeholders/index.html>
10. Tufts Center for the Study of Drug Development ,<http://csdd.tufts.edu/>