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# **Utilizing Siebel Clinical CTMS, RDC 4.5.3 OnSite and AERS 4.6.1 in the greater APAC region with multibyte charactersets**

Presented by  
Sunil G. Singh  
Dr. Letian Liu  
of DBMS Consulting



## Acknowledgements

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- Thanks to the audience members for attending.



## Assumptions/Scope/Disclaimer

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- Scope: Context is within the Oracle Clinical/TMS/RDC/AERS/CTMS product sets
- Assumption: audience is familiar with the OC NLS option and its basic functionality
- Disclaimer: Any comments about the use of OLS in APAC and on the future direction of NLS OLS and are the **opinions and internal research** of DBMS Consulting, and are not based on any written or verbal statements from Oracle itself, and should not be construed as any statement of direction or fact from Oracle itself.



# Agenda

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- Examination of the root cause of the demand for Oracle Life Sciences Applications (OLSA) in Asia-Pacific (APAC) region (except Japan and India).
  - Economic Growth in APAC => Increased Conduct in Clinical Trials => Increasing/existing need for Local language support by CDM/CTMS/EDC/PV systems
  - Japan and India are excluded because OLS currently supports Japanese with the NLS option, and India is the fastest growing market for OLS which is English based.
  - Examination of Greater China region specifically
- Examine some multi-byte capabilities which exist today in the OLS applications, although not fully supported
  - Examine the current locally-based Oracle Life Sciences (OLS) customers in APAC and their demand and use of multi-byte character sets.
- Suggestions for some possible logical steps for Oracle to meet this ever increasing demand for multi-byte and NLS-capable OLSA.
  - Options should be based on BOTH translation capability and native language capabilities
  - Support for multibyte languages should be generalized and not performed on a case-by-case basis



# Background and Overview

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- Strong Economic growth and expanding population in Asia
- => Leads to rapidly growing Life Sciences Market:
  - Increased presence of Global Large Pharmas, Medical Device and Contract Research Organizations (CROs)
  - Local emerging Pharmas, both Generic and Research Based
  - Local emerging CROs serving both Global and Local pharmas
  - Increased regulatory scrutiny of Food and Drug Products
- => Increasing number of clinical trials conducted in Asia
  - Large patient population available at lower costs per patient
  - Availability of skilled medical resource and clinical data management resources
  - Increased government initiatives to improve public health and disease control
- => Increasing and/or existing need for local language support by Clinical Data Management (CDM)/Electronic Data Capture (EDC)/Clinical Trial Management (CTMS)/Pharmacovigilance (PV) systems.
- => Specific functionality is required from Oracle Clinical, TMS, RDC and AERS to meet this increasing demand
  - A translation approach only is not sufficient
  - Multibyte support for several languages will be required, but support for Simplified Chinese represents a specific large demand from Mainland China



## Looking at Economy in ASEAN & Greater China

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- Recent economic data suggest, over the past few years, alongside modest (1-3% / year) economic growth in much of the developed world, the economies of Greater China (Mainland China, Hong Kong, Macau and Taiwan) and Southeast Asia (collectively called Association of South East Asian Nations or ASEAN) have expanded rapidly, with many countries achieving growth in the double digits.
- Although the per capita Gross Domestic Product (GDP) of Indonesia, Thailand, the Philippines, and Malaysia is still low by Western standards, real overall growth in GDP is considerably higher than in most Western countries and is projected to remain strong well into the 21st century.

Source: "Asia's Emerging Pharmaceutical Markets: A Look at China, Indonesia, Thailand, the Philippines, and Malaysia" by Ames Gross; published In Spectrum, a Publication of decision Resources, Inc.



## Looking at Economy in ASEAN & Greater China (2)

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- According to The Economist's forecast of global economies, by the year 2020, China, Indonesia, and Thailand will rank as the first, fifth, and eighth largest economies, respectively, in the world. The World Bank estimates that over the next ten years, East Asia (excluding Japan) will grow twice as fast as any other region in the world.
- High economic growth and increased wealth have meant more available cash to spend on health care in these countries.
- **This trend is likely to continue as the populations in Mainland China and Southeast Asia become increasingly prosperous in the coming decades. In fact, health economists are predicting that some of these nations will be among the world's top ten health care markets by 2020.**

Source: "Asia's Emerging Pharmaceutical Markets: A Look at China, Indonesia, Thailand, the Philippines, and Malaysia" by Ames Gross; published In Spectrum, a Publication of decision Resources, Inc.



## Mainland China: Specific Needs for Safety Monitoring Systems

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- Mainland China can be considered a global superpower today:
  - 40 Billion USD for the 2008 Beijing Olympics, the most ever
    - [http://en.wikipedia.org/wiki/Beijing\\_Olympics](http://en.wikipedia.org/wiki/Beijing_Olympics)
  - 1 Trillion USD in foreign currency reserves
    - [http://www.bloomberg.com/apps/news?pid=10000087&sid=aIJ7mKLQ01rg&refer=top\\_world\\_news](http://www.bloomberg.com/apps/news?pid=10000087&sid=aIJ7mKLQ01rg&refer=top_world_news)
  - Growing Human Space Program with multi-day space missions
    - [http://online.wsj.com/article/SB122235022366575103.html?mod=googlenews\\_wsj](http://online.wsj.com/article/SB122235022366575103.html?mod=googlenews_wsj)





## Mainland China: Specific Needs for Safety Monitoring Systems

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- Food safety and product safety continue to be significant issues
  - Global impact as Mainland China is an exporter of food and consumer products
  - Domestic impact as confidence in local food production is in question
    - <http://www.guardian.co.uk/world/2008/sep/22/china1>
- Clear need for safety reporting and monitoring systems throughout Mainland China, such as Oracle AERS



## **Current OLS Support in MultiByte Languages**

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- Siebel CTMS: Supports several multibyte languages, since CTMS is built on top of the Siebel CRM architecture
- RDC 453 OnSite: Existing NLS support model is pending, but will only support Japanese Kanji
- AERS 461: NLS support for other languages, but requires some customizations.

## **Suggestions for 2 Approaches for NLS-capable OC/RDC/TMS**

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- Only Japanese Kanji is enabled in the OC/TMS/RDC option currently. This requires a replicated environment for translation into English for studies which are conducted in both English and Japanese.
  - If an OC instance is NLS enabled and owns the Global Library, translation of definitions and of Patient data is possible. The only restriction of this approach is that studies can only be conducted either in English or in Japanese, but not simultaneously in both languages (conduct in both languages requires a replicated environment in OC 4.5.2)
- For the Global OC/TMS/RDC customers who require translation capability, the current NLS functionality for OC/TMS/RDC must be extended to include other languages, not only Japanese Kanji.
  - If these customers require the capability to conduct the same study in both English and another language, there should not be a requirement to deploy the OC Replication option
  - This is especially difficult for large Global customers who have promoted a single-instance global use and maintenance strategy within their organization.
- For the locally based regional potential OC/TMS/RDC customers, such as local pharmas, CROs and Government customers, there must be 100% localized version of OC/TMS/RDC which does NOT require an intermediary step for English development, design or translation of studies or reports.



## Current Technical Multibyte Capabilities of NLS

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- Assuming UTF8 based instances, the following functionality is already possible, although not necessarily supported for multi-byte charactersets:
  - Siebel CTMS: Protocol Setup and Data Entry is possible once UTF8 instance and character set is defined. Trip reporting poses some challenges, depending on configuration.
  - AERS: Customization of the Case Screens are already possible. Data Entry is possible. Reporting is possible if XML, not PDF, based rendering is used.
  - RDC OnSite: Data Entry is possible. Layouts and PDR are not possible, since this uses the OC Application Tier/Reporting Server.



## Current Locally-Based OLS customers in APAC outside Japan and India

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- To our knowledge, outside of India and Japan, there are four existing locally based OLS users in APAC:
  - Two in Singapore which are part of the SingHealth Singapore government health care system
    - All trials currently conducted in English
  - One in Singapore and Indonesia (near production)
    - All trials currently conducted in English
  - One in Taiwan which currently uses RDC Classic Mode in Traditional Chinese, but faces many difficulties with
    - Using Batch Data Loader
    - Multiple page Data Entry layouts
    - Generating Patient Data Reports
    - Obtaining support because servers are built in Traditional Chinese Windows OS
- Other users within APAC are based on global users who have regional presence in APAC, but not based in APAC
- **OPINION:** This small number of users in APAC is not due to small demand, but lack of support for local languages



## Potential OLS market throughout the APAC if Multi-Byte Support was Available

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### ■ **OPINION:**

- Adaption of Oracle AERS by the Ministry of Health (MOH) in Mainland China as a strategic global AE and SAE reporting solution
- At least 12 CRO companies in China, Taiwan, Singapore, Malaysia, Vietnam and Thailand and other APAC/ASEAN countries.
- Local pharmaceutical companies in Indonesia, Philippines and Korea which are expanding their research and discovery capabilities.
- Government initiatives for public health research and clinical trials in Indonesia, Philippines, Vietnam, Thailand and Malaysia



## Potential OC/RDC market throughout APAC if Chinese Support was Available Today

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- **OPINION:**
- Potential for RDC page studies on the order 1,000,000+ pages within 2 year of the release of a Simplified Chinese-enabled RDC 4.5.3 On-Site release from Global Pharma-related CRO activity alone.
- At least 10 large Global Pharmas who are currently OLS customers who conduct studies in Mainland China or Taiwan today.
  - Estimated that 50% of these pages will be driven towards CROs who have regional language capability = 1,000,000 pages. Since these some Global Pharmas are entrenched in OLS, they will require that the CROs conduct these studies in OLS with a regional language capability (assuming it exists).

MNC: Multi National Companies, ZRC: Zero Footprint Client



## Potential OC/RDC market throughout APAC if Chinese Support was Available (2)

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- **OPINION:**
- Estimated that the potential "best-case" scenario for MNC-related CRO activity for RDC is at 10,000,000 pages, due to the large number of patients with various medical indications which are readily and cheaply available in China.
  - This is based conservatively at estimating a similar number of paper-based CRF pages which are in use at India-based CROs which use OLS today, and assuming that they would obviously be deployed in Chinese via RDC ZFC.
- Estimated that the existing CROs and customers will have 50% year over year growth.
- Estimated that additional CROs as well as Government institutions in Singapore, Taiwan and Mainland China will also acquire RDC ZFC as this product becomes a "de-facto" standard for the conduct of clinical trials in APAC and is demanded by sponsors.





# Potential AERS Market in Mainland China

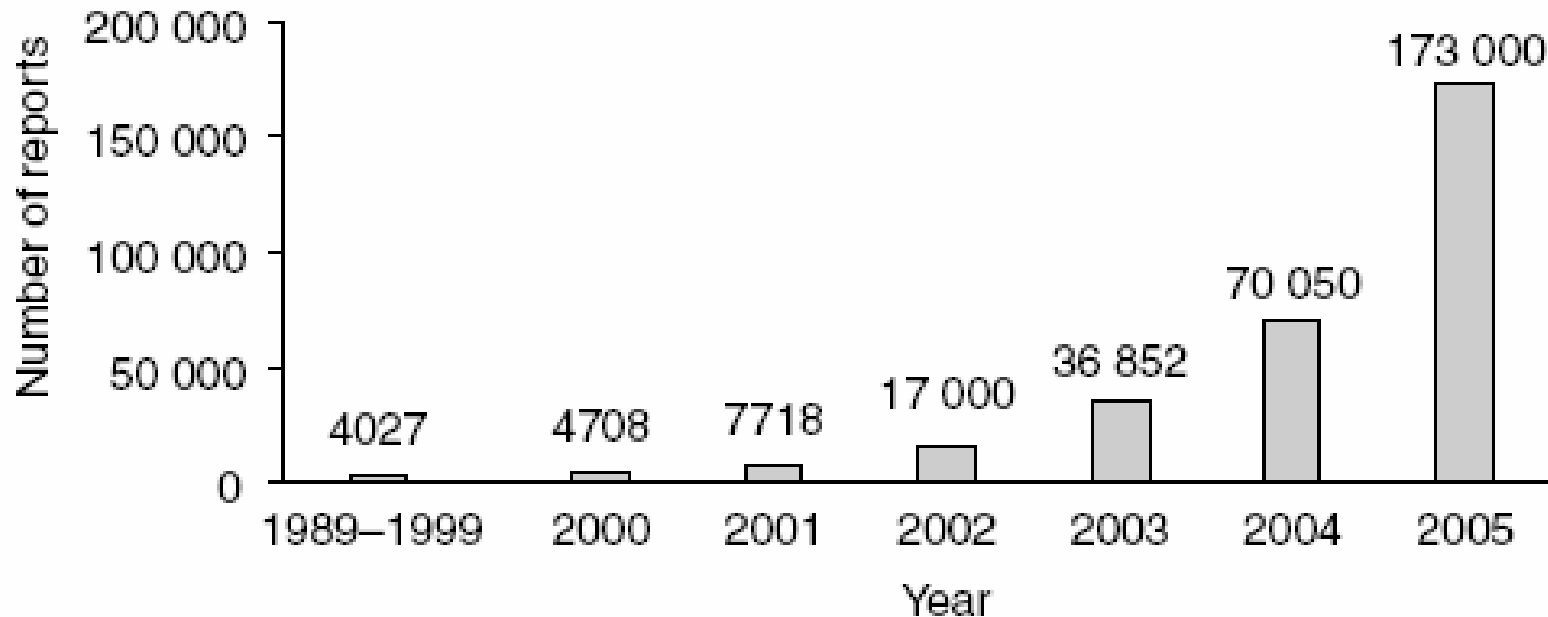
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- The overall increase in drug usage inevitably results in more ADR events. ADR incidence rates in hospital patients in China have ranged from 10% to 30% during the period in which ADR records have been kept. Consequently, greater attention is being paid to ADR issues, not only by the Chinese government but also by the healthcare professionals and consumers.
- Despite the dramatic increases in China's ADR reporting over the past few years, both the source and the number of ADR reports remain limited. Hospital healthcare professionals remain responsible for approximately 99% of all ADR reports.

ADR: Adverse Drug Reaction



# Potential Market for AERS in Mainland China



Total number (for both Western and traditional Chinese medicines) of adverse drug reactions reported between 1989 and 2005

Source: An Overview of Adverse Drug Reaction Monitoring in China, Int J Pharm Med 2006; 20(2): 79-85



# Sample of the Chinese ADR report

附表 1

制表单位: 国家食品药品监督管理局

药品不良反应/事件报告表

新的  严重  一般      医疗卫生机构  生产企业经营企业  个人     编码

单位名称:                                         部门:                                         电话:                                         报告日期:                                         年    月    日

患者姓名		性别:男 <input type="checkbox"/> 女 <input type="checkbox"/>	出生日期:      年 月 日	民族	体重 (kg)	联系方式
家族药品不良反应/事件:有 <input type="checkbox"/> 无 <input type="checkbox"/> 不详 <input type="checkbox"/>				既往药品不良反应/事件情况: 有 <input type="checkbox"/> 无 <input type="checkbox"/> 不详 <input type="checkbox"/>		
不良反应/事件 名称:		不良反应/事件发生时间: 年 月 日		病历号/门诊号 (企业填写医院名称)		
不良反应/事件过程描述 (包括症状、体征、临床检验等) 及处理情况:						

**All reports are paper based.**

Source: State Food & administrate China website



## Developing a Localized OC/TMS/RDC option

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- For E-Business Suite Apps 11i/12i and Siebel CRM (including Siebel Clinical), there is already full support for localized language use, which means:
  - No required translations to/from English
  - No base architecture components running in English
  - All Forms, including Menu Bars, are displayed in the local language
  - All Error Messages, Pop-up Dialogues, Message texts are displayed in the local language
  - All Reports produce output in the local language
  - All On-Line Help is searchable and displays in the local language
  - All documentation is available in the local language
- Additionally, these products have localized business functions available, such as local tax calculations



## **Developing a Localized OC/TMS/RDC option (2)**

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- Since this is already possible to develop in the broader Oracle product sets, it must be extended to the OC/TMS/RDC level
- While the Fusion initiative will eventually solve this problem, this timeframe is too long
- Local pharmas, CROs and Governments require a solution immediately as they conduct local language clinical trials on paper today



## Developing a Localized OC/TMS/RDC option (3)

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- Since Siebel Clinical has already the functionality to design a visit and protocol schedule, and it can manage sites and investigators well, and it has a AE collection module, it is the closest in functionality to OC.
- Using the Siebel architecture, one possible strategy is to extend the already existing Siebel Life Sciences framework to include a component to replace Oracle Clinical entirely.
  - This means a fully functional CDMS, equivalent to OC's Discrepancy Management and Data Management capabilities with multi-language support, but not necessarily having a translation capability between languages.
- This would also open the possibility to have Siebel integrate directly with RDC 4.5.3 OnSite, since the Application Tier technology stack (AS 10g Release 2) is compatible with the Siebel Application Server technology component.
- While this might be in line with the broader Fusion initiative, the suggestion is to have an aggressive strategy to make this possible, similar to the rapid development effort to create the RDC 4.5.3 OnSite release itself.



## **Suggestion for enablement of Multi Character AERS for China**

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- Customization versions of Oracle AERS are required to both support the translation requirements of Chinese to English for the WHO Collaboration Programme and China State FDAs (one national and 31 regional authorities)
- The customization of AERS in Chinese is theoretically possible today in both AERS 4.5.2 and AERS 4.6 because of the flexibility of the FAT/Workflow configuration and native UTF8 support.
  - Only some of the core labels in the Menu Bar for Case Entry and the external Oracle Form itself can not be modified.
- Custom reports can also be made based on the Chinese ADR report. But support from Oracle is a key requirement in order to build confidence and acceptance of these reports by local hospitals to be used within the Chinese SFDA regulatory system



## Conclusions

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- Pharmaceutical / Healthcare Industries, CROs and Government institutes in APAC area have an immediate need for local language support for the conduct of clinical trials.
  - This support is not available in the current implementation of OC NLS and might not be available for quite some time if corresponding enhancements are only implemented together with or after the Fusion migration.
  - However, implementing Local Language support for Asian languages in near future would be a definite competitive advantage for OC NLS or OLS respectively.
  - Waiting for a long term option for several years until a Fusion release is available could mean those local pharmas, CROs and Government institutes requiring a local language solution might go elsewhere to meet their internal clinical trial demands.
- A two part strategy should be undertaken immediately for:
  - Extending the current OC/TMS/RDC NLS option to more easily include additional UTF8 languages.
  - Building a local language only version, perhaps based on the Siebel architecture, which can be used by local pharmas, CROs and Governments in the near term without translation requirements.
- If no other option is immediately available for broad level multibyte character support, then
  - Developing an OC/TMS/RDC NLS option in Simplified Chinese will be immediately strategic and will help to empower the usage of the NLS OLS throughout the APAC.
- Immediate multibyte characters usage can be enabled in AERS with some customisations. This should be part of a broader strategy of support for AERS in the previously mentioned multi-byte languages.





## **Additional Questions ?**

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- E-mail: [singh@clinicalserver.com](mailto:singh@clinicalserver.com)  
[liu@clinicalserver.com](mailto:liu@clinicalserver.com)
- Call: US +1-860-983-5848  
US +1-732-690-3124  
China +86-134-0212-4879
- Electronic copies will be posted on the OCUG Intranets Site and [www.clinicalserver.com](http://www.clinicalserver.com)