Implications for the future direction of the OLS NLS option: An examination of Greater China and ASEAN/APAC countries use of the OLS today

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- Thanks to the audience members for attending.

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Assumptions / Scope / Disclaimer

- Scope: Context is within the Oracle Clinical/TMS/RDC/AERS 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.

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Agenda

- 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
- Evaluate the potential OLS market throughout the APAC requiring multi-byte OLS capability.
  - 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 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

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Background and Overview

- 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

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Looking at Economy in ASEAN & Greater China

- 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.

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Looking at Economy in ASEAN & Greater China (2)

- 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.

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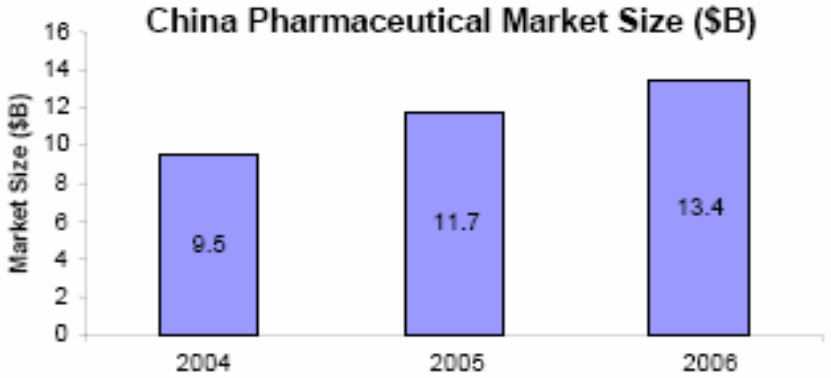
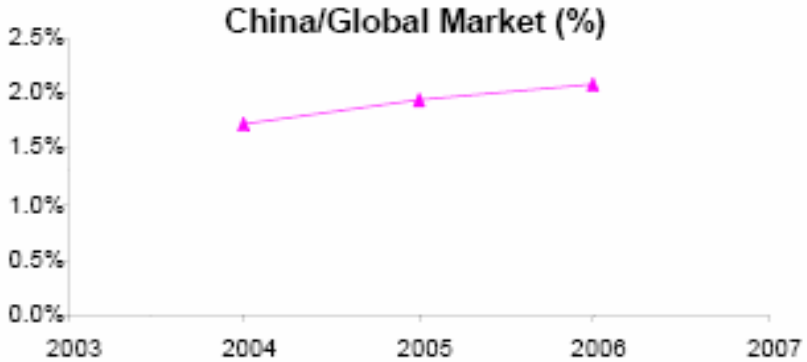
Mainland China vs. Global Pharma Market: Currently 2% = Large Growth Potential

China is only 2% of global pharmaceutical market!





Source: IMS Health

Source: " China: Entering Global Life Sciences Center Stage", Impact China III Conference 2007, Shanghai by Dr. Jonathan Wang Burrill & Company

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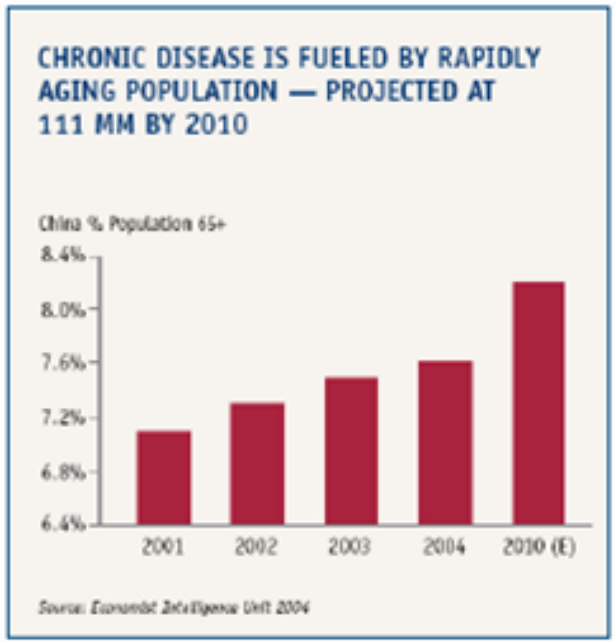
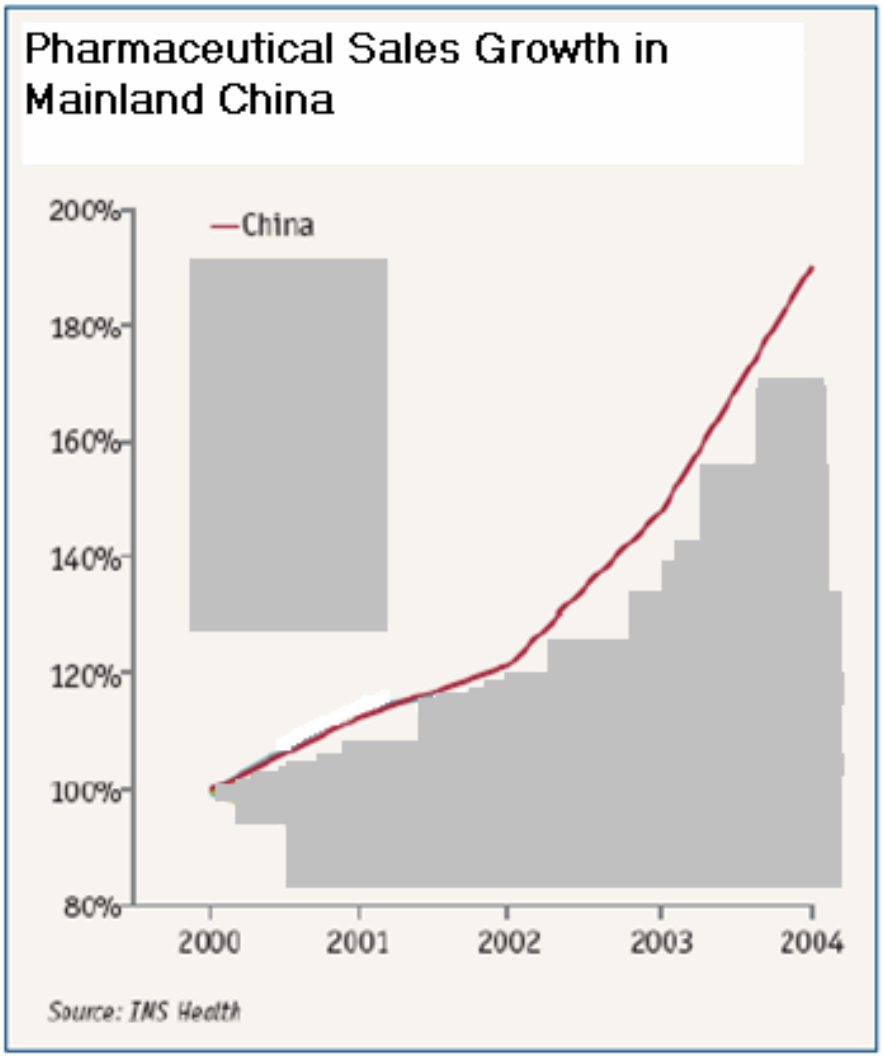
Mainland China Pharmaceutical Market Growing at 2-4x Global Rate





Source: " China: Entering Global Life Sciences Center Stage", Impact China III Conference 2007, Shanghai by Dr. Jonathan Wang Burrill & Company

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Pharmaceutical Market Growth in ASEAN

- Thailand Pharmaceutical consumption is over US$ 1.5B with percentage growth in double digit figures, having the 4.6% population as of Mainland China.
- The Philippine pharmaceutical market valued at US$1.3B, having 7% population as of Mainland China.
- The Indonesia pharmaceutical market valued at US$350M, having 17.8% population as of Mainland China.
  - **The Indonesia market remains characterized by its competitiveness. Pharmaceuticals imported in finished form play only a small role in the market, being restricted to supplies of highly advanced products. Most requirements are locally manufactured using imported raw materials.**
- The Pakistan pharmaceutical market valued at US$1.5B, having 12.5% population as of Mainland China.

Source: PriceWaterHouseCooper publications.

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Global Pharmas are also Increasing R&D Activities in China

26 May 2006

AstraZeneca Announces $100 Million R&D Investment in China

Pfizer inaugurates R&D center in Shanghai

US pharmaceuticals giant Pfizer Inc. inaugurated a research and development center in Shanghai Monday

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PAGE ONE

Low Costs, Plentiful Talent Make China a Global Magnet for R&D

By KATHY CHEN and JASON DEAN
March 13, 2006; Page A1

BEIJING -- Multinational companies, drawn by a huge and inexpensive talent pool, are pouring money into research and development in China -- a trend that promises to broaden the country's huge role in the global economy.

Source: " China: Entering Global Life Sciences Center Stage", Impact China III Conference 2007, Shanghai by Dr. Jonathan Wang Burrill & Company

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Demand for Multi-byte Character Support in Life Sciences in APAC

- From our internal research, we suggest the following examples are representative of the Multi-byte Character demands within APAC:
  - The two market leading EDC vendors have a number of strategic alliances with government health agencies in APAC, including the State Food and Drug Administration (SFDA) in China, where pilot tests are being implemented
  - The SFDA in China currently uses an internally built system for managing Adverse Drug Reports (ADRs) in Simplified Chinese, but does not have any automated method of collating and assessing these reports
  - In Indonesia, Philippines, Vietnam, Thailand and Malaysia, there are current public-health government initiatives to conduct **local language** clinical trials. Many of these trials are paper based because it is not possible to support EDC trials in some locations.

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Demand for Multi-byte Character Support in Life Sciences in APAC (2)

- A university in Australia currently conducts over 100+ clinical trials for public health studies in Mainland China, using a custom-built EDC interface which runs in Simplified Chinese.
- Currently, recent media events have lead to increasing scrutiny on Food and Drug Safety in Mainland China. This has lead the Chinese Health Ministry to seek out new solutions and collaborations for increasing product safety and public health, including increased cooperation with the WHO.
- In Thailand, there are at least 5 global companies conducting trials related to AIDS. Many of the remote clinical sites must conduct trials in Thai to communicate with the patients, but these CRFs must be translated manually before being used in Oracle Clinical.

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

- To our knowledge, outside of India and Japan, there are three 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 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

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

- **OPINION:**
  - A university institute in Australia currently conducting 100+ trials in Mainland China in simplified Chinese
  - 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

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

- **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 release (Zero Footprint Client or ZFC) 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

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

- **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.

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Potential AERS Market in Mainland China

- 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

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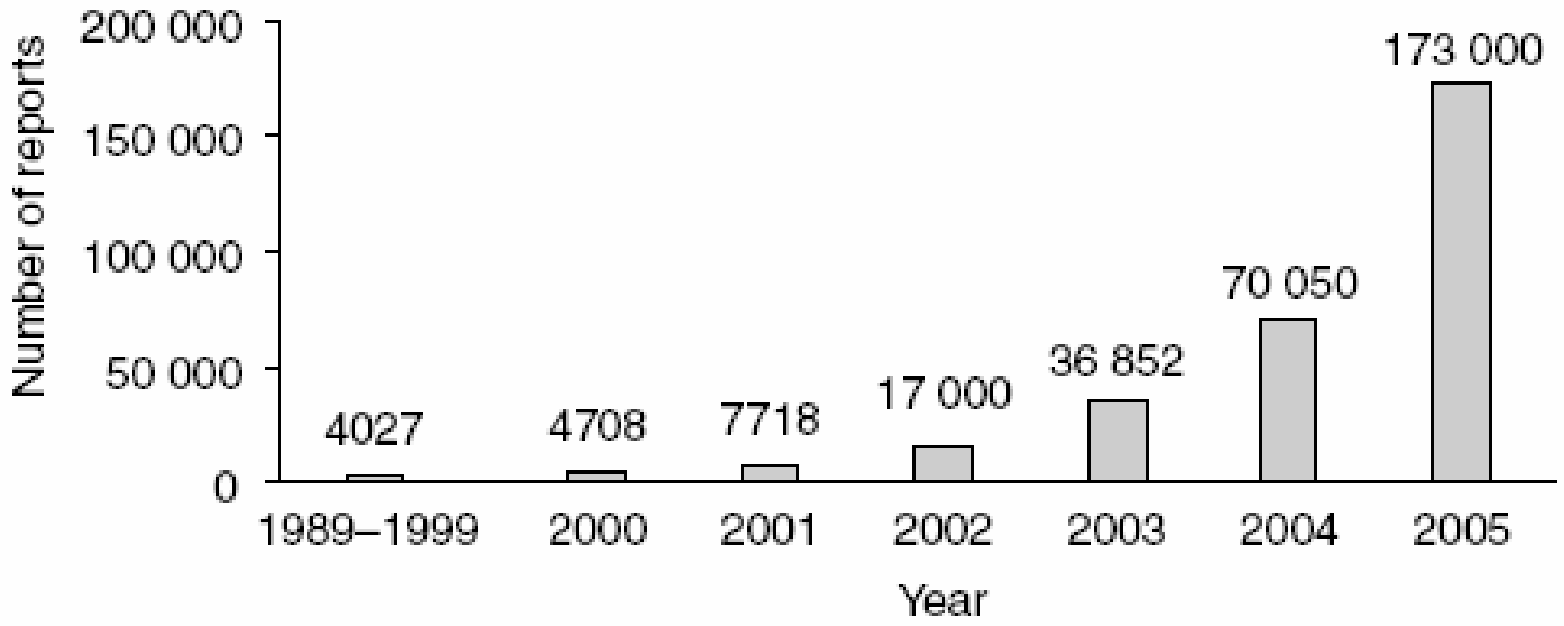
Potential Market for AERS in Mainland China



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

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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☐女☐	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☐无☐不详☐			既往药品不良反应/事件情况: 有☐　无☐ 不详☐		
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

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

- 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 pharms, 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.

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Extending the current OC/TMS/RDC NLS option

- From the Oracle Clinical 4.5.1 NLS Users Guide, pp 1-1 to 1-2, the OC NLS option allows users to:
  - Manually translate (enter local language translations for) numerous global language objects.
  - Copy local language translations for objects, saving time and ensuring translation consistency.
  - Create local language DCM layouts.
  - Enter or batch-load data in the local language.
  - Manage discrepancies in the local language.
  - Generate reports (discrepancy history, response history, and DCF reports) containing local language values.
  - Translate local language text data to English for analysis with non-NLS data.
  - Extract local language data for analysis.
  - Create Local Language Graphic Layouts and generate Local Language DCI Forms for performing NLS Data Entry using Oracle Remote Data Capture (RDC).

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Extending the current OC/TMS/RDC NLS option (2)

- All of the previous functionalities should be available in a broader NLS context, specifically
  - Even though the underlying RDBMS and Application Servers support UTF8 charactersets, there is a requirement that each new supported language needs specialized development effort
    - For example, Pro*C modification of RXCDXBVB, RXCBEBLT and RXCBVBVS is required to support a new language.
  - This approach needs to fundamentally change so that a minimal amount of effort should be required to extend the current NLS capability to any language in the UTF8 characterset
  - Furthermore, this functionality should be enabled as a customisation by the OC/TMS/RDC customer or outside vendors through APIs or documented procedures available in eTRMs or Metalink.
    - In this way, the user community is not restricted by development resource from within Oracle itself.
- OS level support for all UTF8 languages should be explicitly listed as past of the NLS supported configurations, not only English and Japanese
  - This will immediately open the possibility of attempts to perform Batch Data Loading and SAS Data Extracts directly to and from an NLS-enabled OC/TMS/RDC environment

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Developing a Localized OC/TMS/RDC option

- 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

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

- 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

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

- 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 ZFC, 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 ZFC release itself.

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Suggestion for enablement of Multi Character AERS for China

- 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

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What Languages should be supported for multi-byte use in APAC?

- **OPINION:**
- Simplified Chinese
  - If there was only a choice to bring online one language in OC/TMS/RDC, choosing Simplified Chinese would open the largest number of possibilities for existing users and potential users throughout APAC and globally
- Traditional Chinese
  - Allows more possibilities in Hong Kong, Taiwan, Singapore and any region with a large Chinese population which emigrated from China before 1949.
  - Since there is already one user in Taiwan running Traditional Chinese today, it only makes sense to support current user base
- Thai
  - Due to the large number of HIV-related trials, this would open the next largest group of users and sites currently not available to the OLS user base

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What Languages should be supported for multi-byte use in APAC? (2)

- Indonesian
  - Large local pharmas as well as Government initiatives and a very large population
- Vietnamese
  - Government Initiatives and Global Pharmas are making large scale trials possible with a large amount of foreign investment from China and EU
- Korean
  - Major Pharmaceuticals manufactures and CROs exist locally which use internally developed Life Sciences systems
- Malay
  - Many government initiatives and local pharmas are present which are using paper based studies and internally developed systems
- Filipino/Tagalog
  - Since the Philippines has very large local and global manufacturing, there are government initiatives to increase product safety and consumer testing and reporting. Both languages are required since both are equally used nationally
- Eastern European Languages
  - This is the next largest area of emerging clinical trials in local languages outside of APAC
- Brazilian Portuguese
  - This is the next largest area of emerging clinical trials in local languages in Latin America

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Conclusions

- 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.

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Additional Questions ?

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