GLOBAL Trend and opportunities in drug development

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October 2015

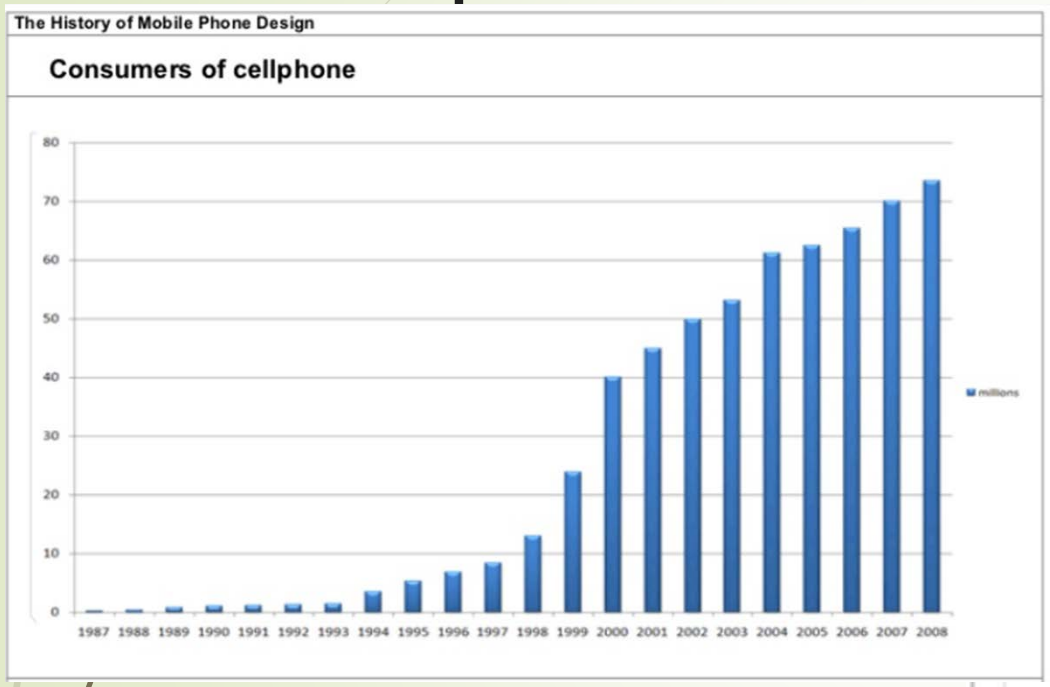
Looking back during last 15 years

- Drug safety became a focus for both regulators and drug developers. Goal = detect safety signal pre-approval. Reduce post approval withdrawal.
  - Pharmacovigilance: Global reporting, data mining, signal detection, etc
  - Specific topics of interest: Cardiac safety, DILI, etc
- Focus on 'Biomarker Qualifications' Effort to use reliable biomarkers in decision making ie HBA1C, Patient Report Outcome (PRO), etc
- Approvals of Biosimilars, Medical Device, Vaccine and combination (such as drug-device) Harmonization effort for global regulators (EMA/FDA) and clinical trial reporting
- Electronic Medical Record (EMR) became mandatory in USA
- Pharmaco-economics. Cost effectiveness. Approval vs reimbursable.
- Clinical operations
  - Risk based monitoring
  - Electronic instead of paper based: electronic data capturing (EDC), Trial Master File (eTMF), Patient Report Outcome (PRO), eCTD, etc
  - Role of social media in patient outreach
- Non clinical activities: Outsourcing trend ➔ Insourcing

Continuing challenges in drug development

	Current status	Potential approach
Rising cost of clinical trials and overall drug development. Low overall return on investment for NCEs	Consider outsourcing. Flexible functional outsourcing model. Me too = lower risk, lower reward. Breakthrough or first in class = high risk, high reward	Increase efficiency (electronic?). Early termination of failed programs. Reduce the number of 'me too' drugs. Focus on real 'unmet' medical needs in sick population? Orphan indications?
Social media and electronic platform for data collection	Safety report via social media = self report? Unclear influence of social media on clinical outcome.	Clear guideline on indirect AE reporting.
Hard to enroll due to low incidence of disease or existing standard of care (SOC)	SOC varies globally and may affect trial design and results.	Clear guideline on orphan indication. Choose indications with inadequate SOC only.
Phase 1 or Proof of concept (POC) studies in patients – hard to find qualified sites	Early patient exposure is a valid strategy but may be operational challenging.	Hybrid model. Ph 2-3 PIs and sites can extend into POC studies with CRU collaboration.
Regulatory timeline – uncertain or too long	FDA turnaround = 30 days. AUS/NZ = only need EC approval for healthy volunteer studies	Accelerate regulatory and IRB approvals. Enhance regulatory personnel support.

Mobile phone technology enable a new platform for data gathering

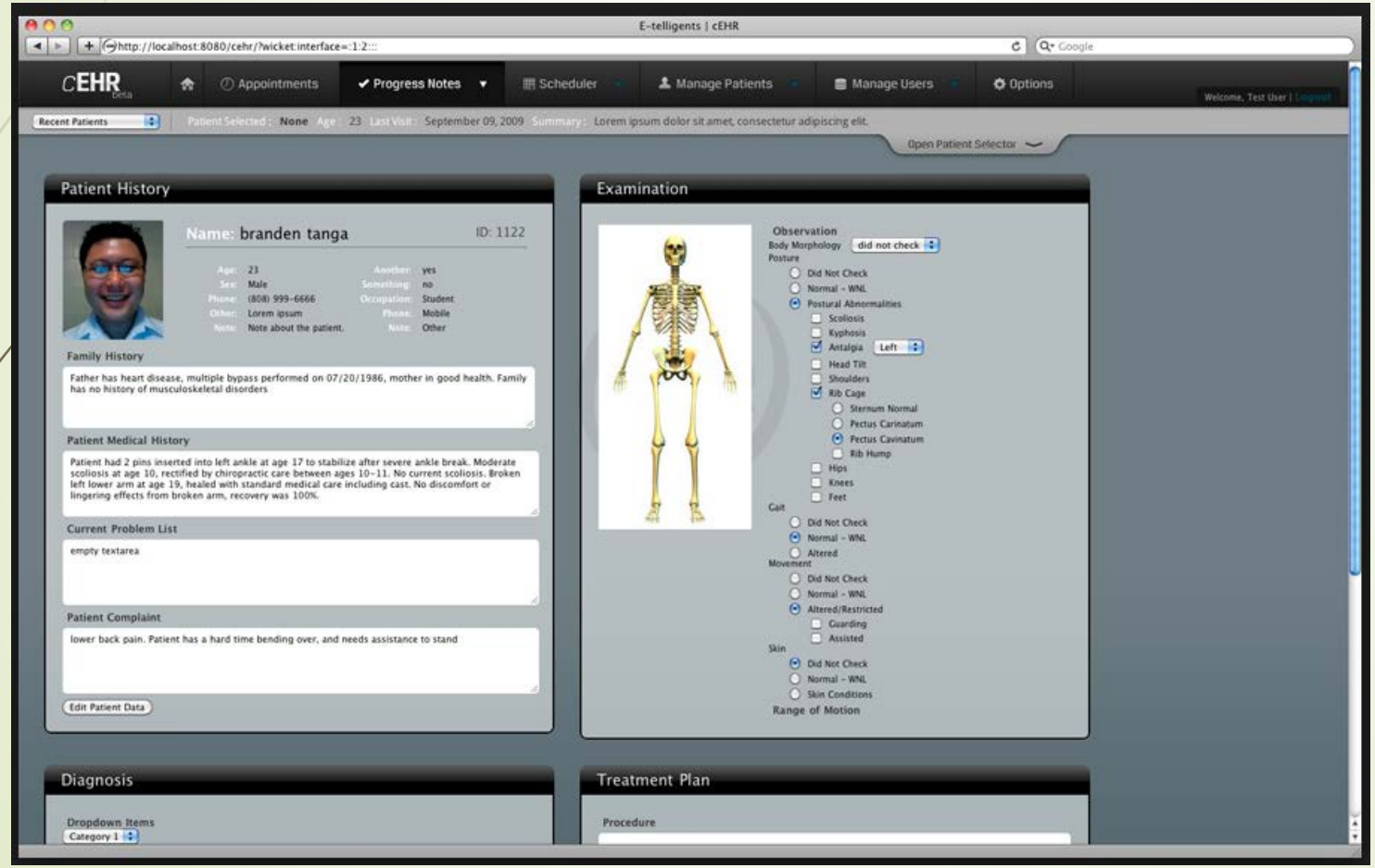


Convergent Devices

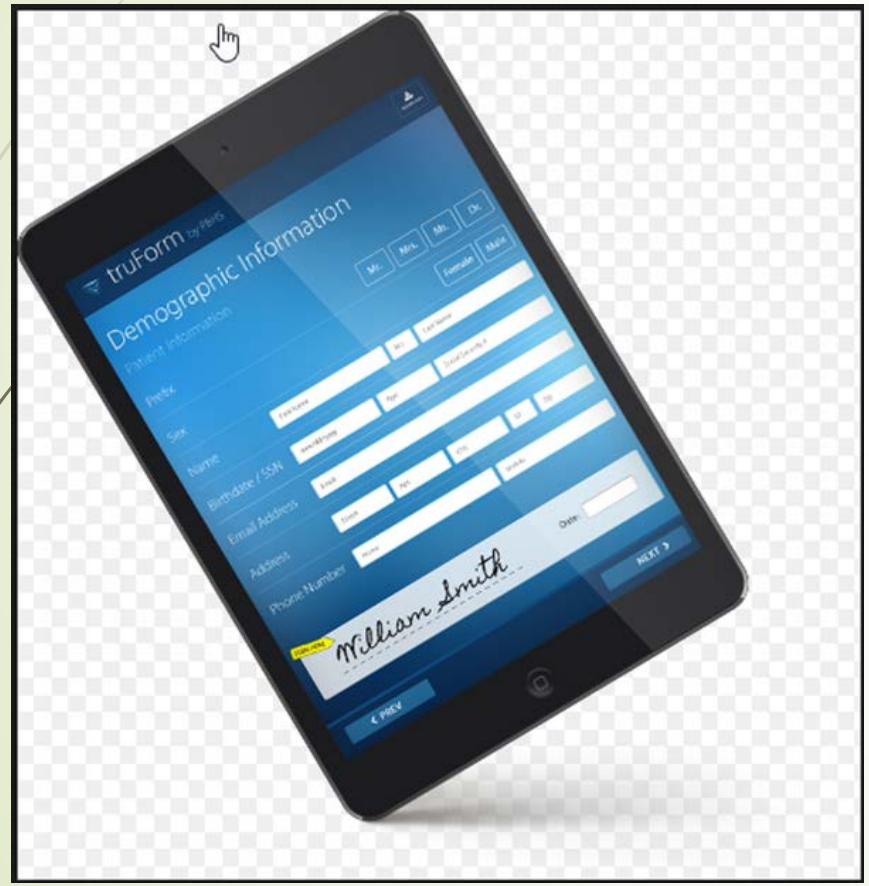
The latest trend is to combine many different types of device in one.

So mobile phones can also be used as PDAs, MP3 players, games consoles and as devices to surf the internet.

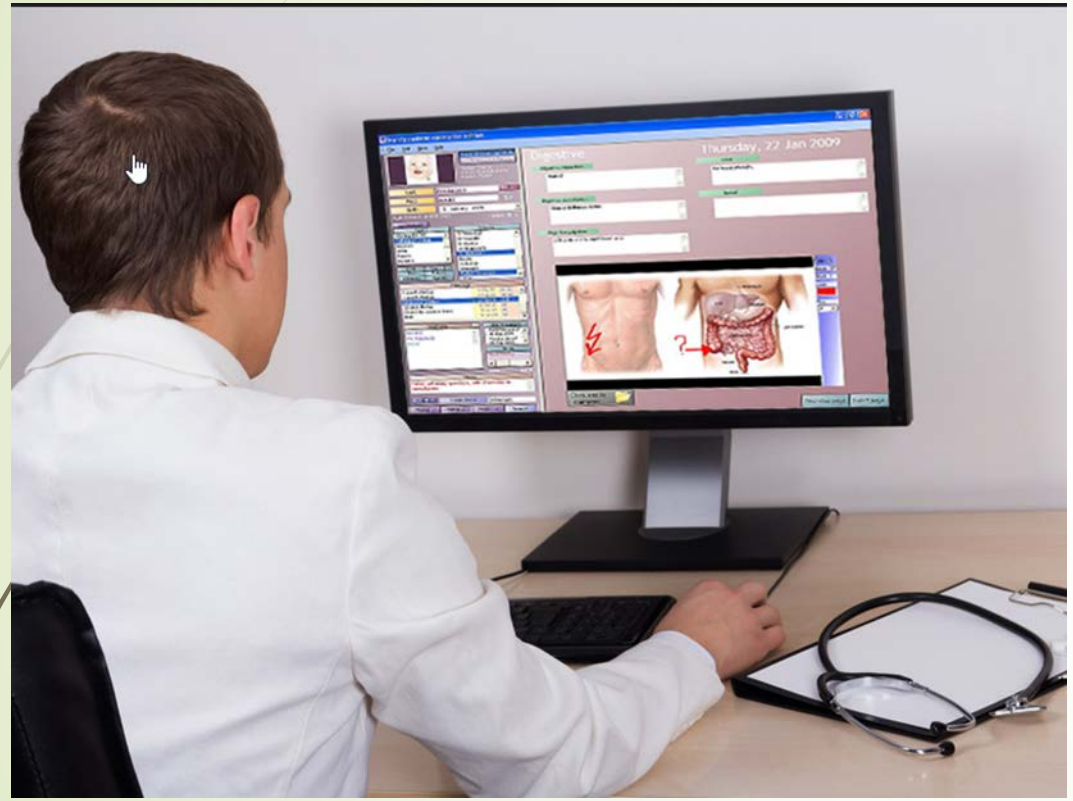
Electronic Health Record



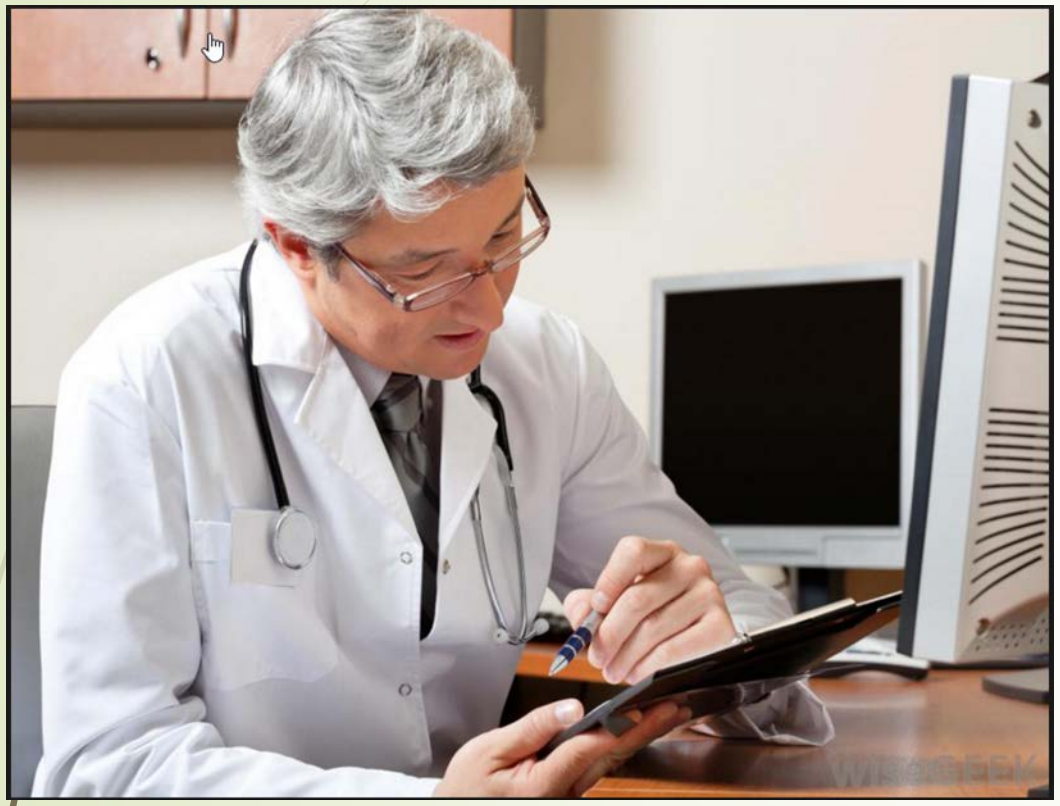
Direct data import or entry by the lab or patients

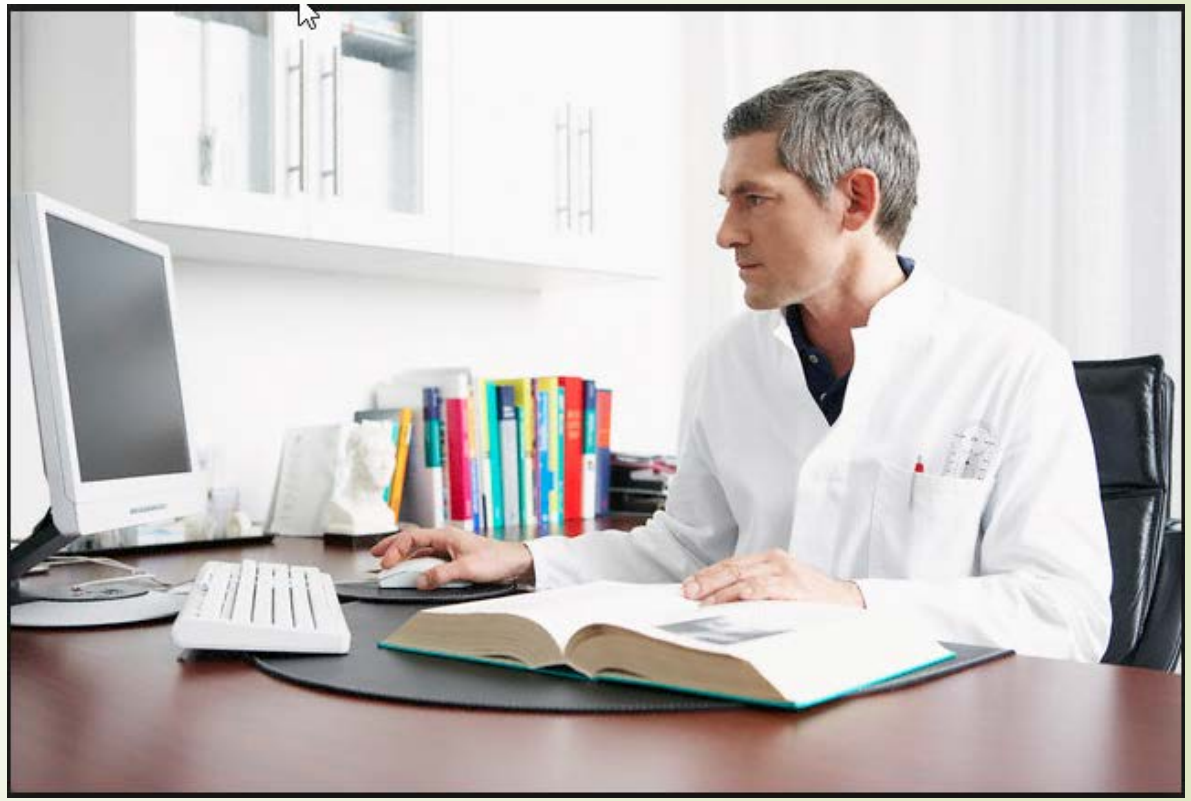


Direct data entry at the site(s)



Real time data review by PIs or sponsor(s





Potential trends in the next decade

- More acquisitions of new (potential) drugs from R&D companies. Commercialize by big pharmas. More partnering to share financial risks.
- Clinical study execution
  - Real time data entry by global sites or patients and review
  - Faster turnaround of results
  - More social media in advertising and recruiting
  - Multiple partners in study implementation: sponsor, CROs, sites, etc
- Payor's perspective (reimbursement) becomes additional hurdle for drug development
- ? Should there be a global standard for drug approval?

What will it take for Thailand to excel in clinical research??

- Collaboration(s)
  - Physicians, Clinical Research Personnel, CRU staff, etc
  - Local lab, special lab, bioanalytic lab, etc
  - Access to special tests for research purpose: imaging, endoscopy, histopathology, etc
  - QA infrastructure
- Electronic capabilities to support EDC, eTMF, eCTD, ePRO, etc
- Reliable and up-to-date medical records and patient database
- Enhance EC and Thai FDA's ability to review and turnaround protocol submission with reliable scientific rationale in a timely manner
- Personnel to manage overall clinical research: at the site level, sponsor monitoring, project co-ordination, data management, report writing, etc
- Business Development: A strong message = why Thailand?