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PhUSE 2018

Implementation of Digital Tools for Real World Evidence Generation and Drug Safety Surveillance

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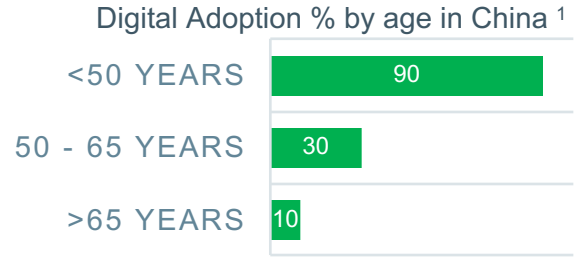
Need for Digital Uptake and Governance in Evidence Generation

Changing Patient Behavior



Digital behavior will slowly become the norm

Convenience and accessibility

1/3 of patients use mobile devices daily to research/ book appointments[2]

"Dr Google"

75% of search paths by patients are related to symptoms, condition terms and management[2]

Medical Data Fragmentation

Clinical data sources are fragmented with increased focus on Direct to patient insights:

- physician recorded medical notes (primary RCT source)
- patient reported outcomes (eg: patient apps)

Increasing focus on APAC

~20% of clinical studies conducted worldwide in the past 5 years are managed in APAC[3]

Proliferation of health apps

Over **318,000** health apps in app stores worldwide (200 are added each day) [2]

[1] China: Internet User Penetration By Age Forecast 2018 | Statistic https://www.statista.com/statistics/369636/china-internet-user-penetration-by-age-forecast/
[2] The Digital Journey to Wellness | 2012 Google/ Compete Hospital Survey https://www.aliad.es/es/archivos/the-digital-journey-to-wellness-hospital-selection_research-studies.pdf
[3] ClinicalTrials.gov

Challenges we faced in implementing digital tools

Patient Behaviour

Fragmented Data

Localised

Digital behavior
- Digital consumption differs
- Touchpoints can vary (eg: WeChat vs Whatsapp)

Regulatory & Legal Compliance
- ICH-GCP
- 21 CFR Part 11
- Audit trail
- Authorization
- Back-up

Data Maturity
- Multiple hospital data sources
- Data integration and analysis integrity

Uniform

Technical Validation	• Software development lifecycle management • Technically sound and compliant – security and infrastructure
Data Privacy	• Data ownership vs access • De-identified patient data
Operational Feasibility	• Solution deployment • Patient access/ support • Consistent data quality

CASE STUDY

Using Technology to Advance Safety Surveillance in APAC

Situation

- New regulations in China
- Mandatory safety evidence to be submitted after 3-5 years of CFDA approval – 3k-5k patients
- Doctors to assess ADRs or SADRs

Challenges

- Under-reporting of ADR/AEs
- Recall limitations / bias under existing long-term follow-up
- Reduced awareness of drug safety profile in real world

Outcome we wanted

- Record symptoms at onset
- Rapid identification of potential adverse events by treating physician
- Visualization of symptom trends
- End-user driven system design and validation

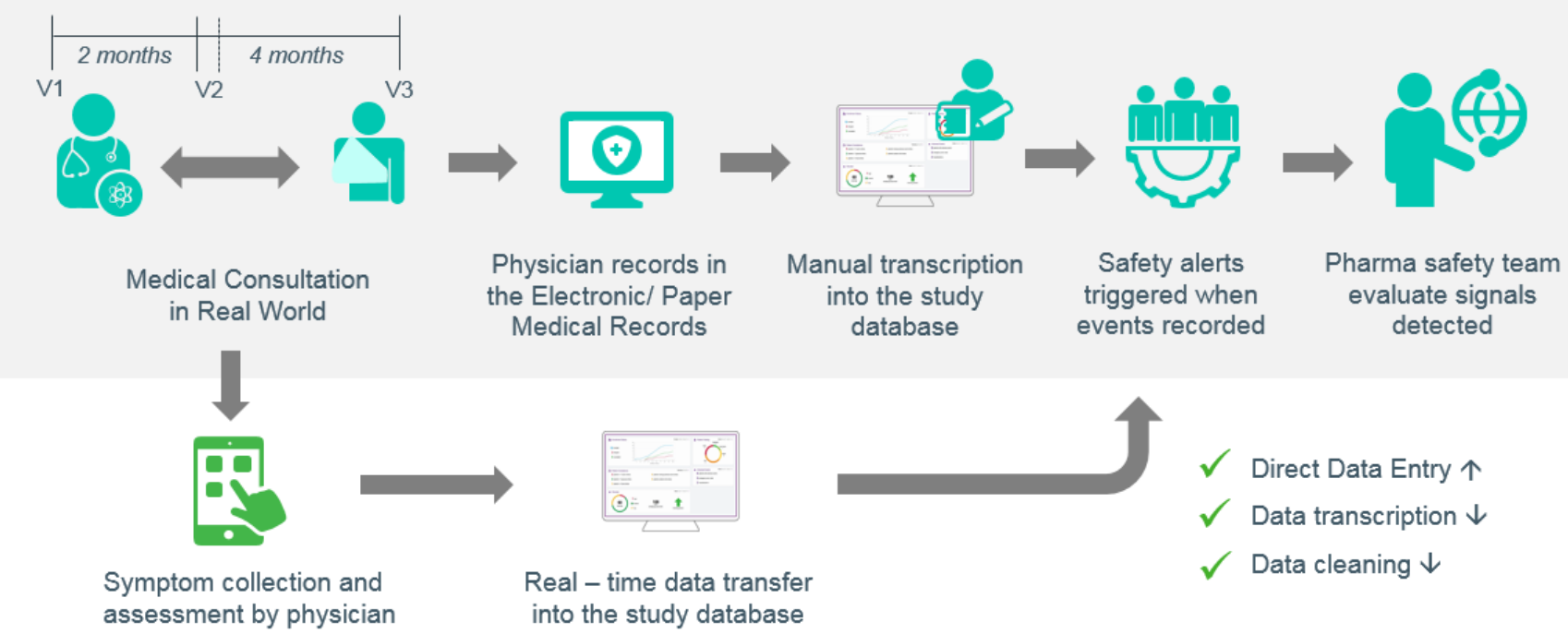
How do we get there?

CASE STUDY

Baseline understanding….

Key question to solve

- What are the various challenges/painpoints – can digital mitigate them?



CASE STUDY

Talking to users

Different stakeholders will have different challenges

- Identified the various stakeholders who are key to the process of safety surveillance studies
  - Challenges
  - Data points needed for assessments
  - Encourage usage

In-Market Validation: Digital Symptom Collection and Adverse Event Assessment

SPONSOR

- Understand the **critical data points/ insights** to evaluate/ generate
- Identify **concerns around** using of **digital patient solutions**
- Discuss **operational feasibility**

DOCTOR

- Understand **current reporting process** and associated pain points
- Discuss the **feasibility of leveraging digital**
- Identify **motivations** for trial participation
- Assess **potential site burden**

PATIENT

- Understand the **current digital healthcare management** routine
- Assess **patient behavior** across indications
- Identify potential areas for **patient burden and barriers for adoption**

OPERATIONS

- Understand the **operational feasibility** of digital solutions
- Update **training and processes** to support systematic and consistent delivery
- Identify potential **risks and mitigations** associated innovative strategies

CASE STUDY

Interim findings

ADOPTION

- Expectation around usage of digital tools – seen as **inevitable**
- Making the best of the situation – **ease of use** and accessibility
- Always **talk to end-users** to verify/validate your hypothesis
- **Education** (content and materials) to support adoption is key
- Increase accessibility to **other peripheral stakeholders** to **reduce site burden** due to data volume

ADAPTATION

- Currently, not all studies can be digitized fully – **hybrid approach**
- **Not all indications** can be suitable for digital
- Consider adaptations to **cater for types of indications**
- **Constant education** is required to reduce site burden and enhance patient experience

Any questions?

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Thank you

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