

RealWorld Data solutions for PMS studies



Future Standard:

- EDC and Paper CRF can be combined into One Database
- ☑ Speedy Set-Up
- Powerful tool for enhancing Data Quality
- ☑ Support MR to monitor Study Progress
- ✓ Most Cost Effective Solution

Advancing PMS Together 🍞





EDC and Paper CRF can be combined into One Database: RealWorld Hybrid System

The RealWorld Data Solution has a Hybrid system which provides the choice between a paper CRF or an EDC study or both. There is a Double Data Entry (DDE) feature to ensure optimum data accuracy. Furthermore the Hybrid system's seamless interface significantly reduces study costs.

2 Speedy Set-Up:2 stage system release

The study can be set-up speedily because the 2 stage system (case registration system & CRF system) release enables patient enrolment to commence while the CRF is being developed. This means that data collection from registered patients can commence as soon as the CRF is released (~ 1 month post registration release).

B Powerful tool for enhancing Data Quality: RealWorld Query Management System (QMS)

A comprehensive Query MS enables frontend edit checks (eCRF only) and complex backend checks (paper and eCRF). Complex backend checks are written and deployed via RealWorld Rulewriter to ensure optimum data accuracy throughout the study. As a result monitoring visits and helpdesk calls are significantly reduced, shortening the time to study completion.

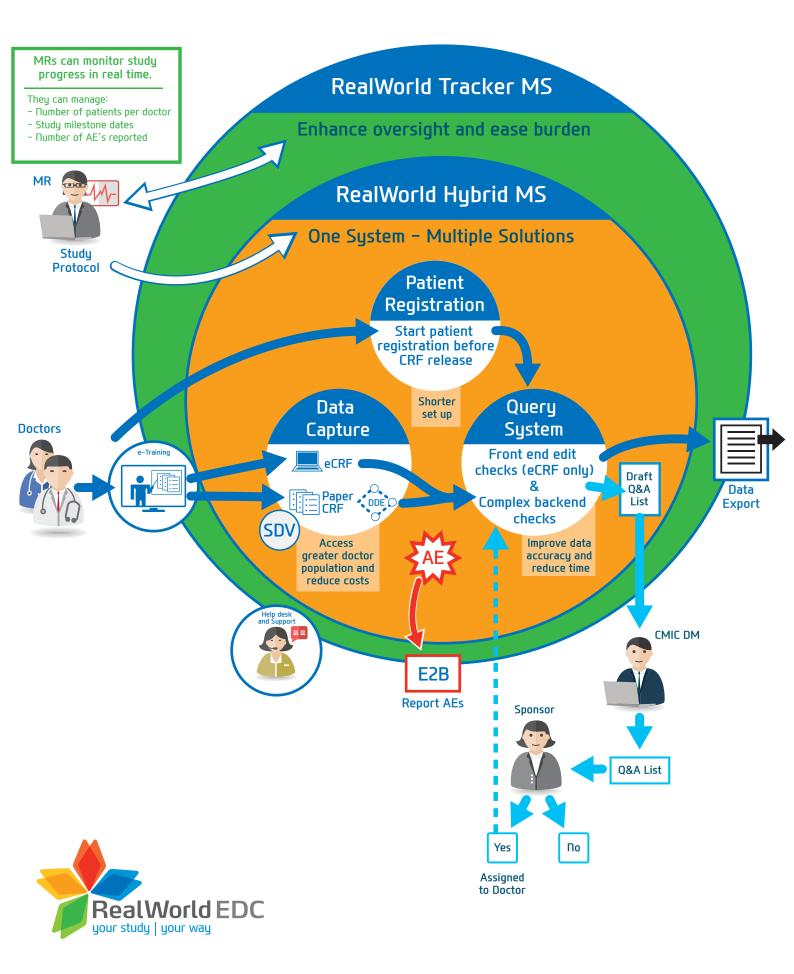
4 Flexible study monitoring system supports MRs: RealWorld Tracker Management System (TMS)

The Medical Representatives (MR) can monitor study progress in realtime. The MR can rapidly identify metrics such as the number of patients enrolled and number of adverse events reported.

5 Most Cost Effective Solution

The RealWorld PMS study solution makes data collection and management simple and affordable. For PMS studies it's seamlessly integrated interface saves time for busy doctors & MRs and reduces study cost.

Trust RealWorld Data Solutions



Overview of the RealWorld Data Solution



Stage 1 of 2: Earlier enrollment to shorten the time to go-live.



調査に関するダッシュボード

登録者	20
未登録者	8
総症例数	28
織計目標症例数	1
登録状況	
音録者	103
完了(最終観察終了)	9
脱落	4
88t	116
目標症例数	10
CRF情報	
未完了	111
署名済み	4
署名待ち	5

Really

orid EDC

患者循弓

61004 01003 プロトコール: Respiratory 実施施設: 1 - Test Site 1 投制: CRC ユーザー: cncrr

根本の ステータス

変換済み・未要名

2880-885

CRFステータス表示

患者基本情報

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04-02-2017

03-02-2017

02-02-2017

	03 11月 2016	
主なスケジュール		
調査開始日	27 5 2015	
最初の症例の登録日	12 8 2015	
登録期間終了日	01 10 2015	
最終症例最終觀察予定日	28 2 2017	
クエリ		
発行ウエリ	23	
問合せ中	3	
完了	20	
有害事象		
有害事象	39	
副作用	14	

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Tracker MS enables the Medical **Representative (MR)** to monitor study progress in realtime.

Query System: improves data accuracy and reduces completion time.

Query System shows open queries on CRF overview leading to simple resolution.





Why choose RealWorld solutions for PMS studies?



Proven track record with leading pharma

For over a decade we have established a global reputation as a preferred vendor of an Electronic Data Capture system for Post Marketing Surveillance (PMS) studies to world leading pharmaceutical companies. Our software has been deployed successfully across Europe including Ireland, UK, France, Netherlands, Germany, Austria, Slovakia and Slovenia. We continue to expand our global outreach – our largest study to date was conducted in Russia by a leading Japanese Pharma company. This study involved over 700 doctors and 21,000 patient visits across 6000km and 6 time zones.



Developed specifically for the Japanese market

We have spent over 3 years tailoring our software specifically for PMS studies in the Japanese market. This has led to the development of the 'RealWorld PMS Study Solution' – exclusively licensed to CMIC in 2017.



Eases Burden on Medical Representatives

The RealWorld PMS study solution's seamlessly integrated interface eases the workload on Medical representatives through increased access to the doctor population, enhanced study oversight, shortened study completion times and reduced study costs.



CDISC certified and 21 CFR part 11 compliant

We recognize the importance of complying with the global gold standard for medical research as well as Japanese ER/ES Guidelines.

RealWorld Data Solutions offer a flexible pricing model.

This economical pricing model makes RealWorld Data Solutions suitable for both small and large studies.

CMIC PMS will be happy to provide pricing for individual studies. Please contact us as detailed below.

