



# CleanWeb

## ePRO WEB

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**e-tools and social networks for epidemiology**

**Paris – 21/05/2013**

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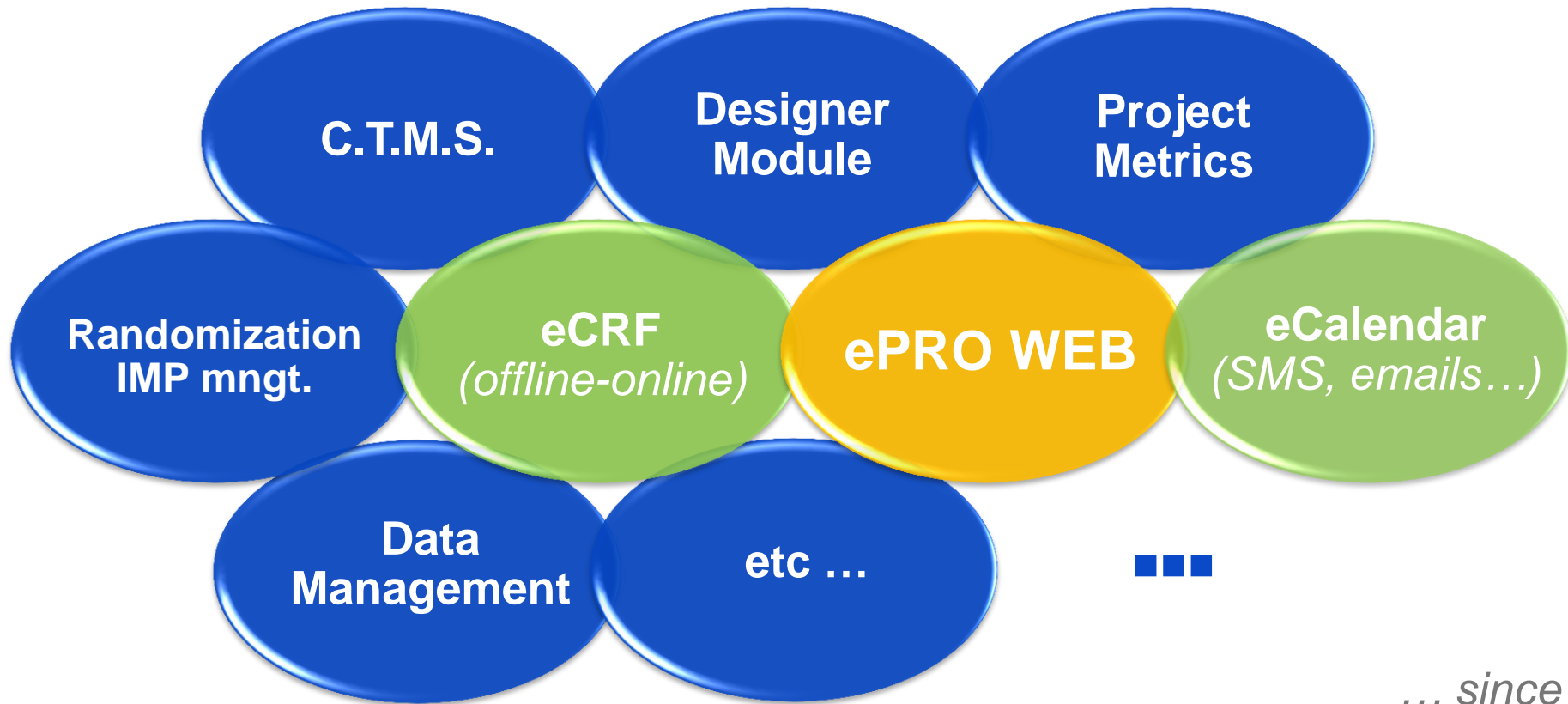
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# CleanWeb

A Global Solution for online management of clinical trials & epidemiology



... since 2003  
SaaS / Licence – 21 CFR Part 11 compliance

# PRO – Patient Reported Outcome



- Patient questionnaires to be filled independantly from the investigator

## Why use ePRO ?

- Increased data quality (i.e. primary study criteria..)
- Real-time data collection → transparency
- Allow subjects additional privacy
- Minimize risk of falsifying data
- Higher compliance rates
- ...



## Paper

- Patient ID ?
- Quality of data, compliance ?
- Logistics ?
- Double data entry process ?
- Flexibility ?



## PDA

- Equipment costs ?
- Logistics ?
- Maintenance ?
- Flexibility ?

# Why ePRO \*WEB\* ?



Subjects complete eQuestionnaires via direct entry on a web site.

- No hardware, no hardware malfunction
- No maintenance (battery, synchronization...)
- Dramatic cost reduction
- Can be associated with an eCRF : data available to sponsor in one database
- Patient uses his own device/computer: ease of use





## Example of study using ePRO

### Study on back pain

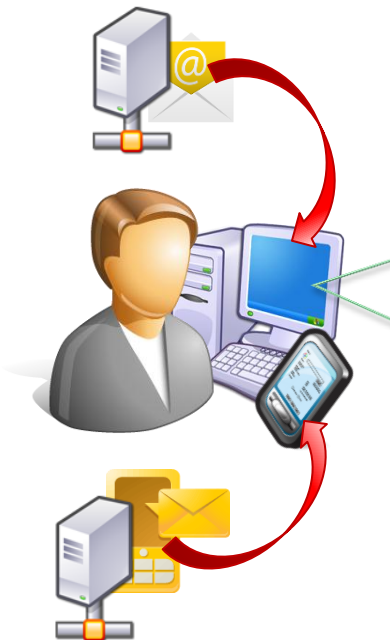
- Inclusion visit
- Pain evaluation every 15 days (ePRO)
- Additional questionnaires at 3, 6 and 12 months (Quality of Life, Disability, Mood...) (ePRO)



## Security and authentication

Contact information saved on a secure server with restricted access rights

Patients / subjects authenticate using a PIN code received by email or SMS

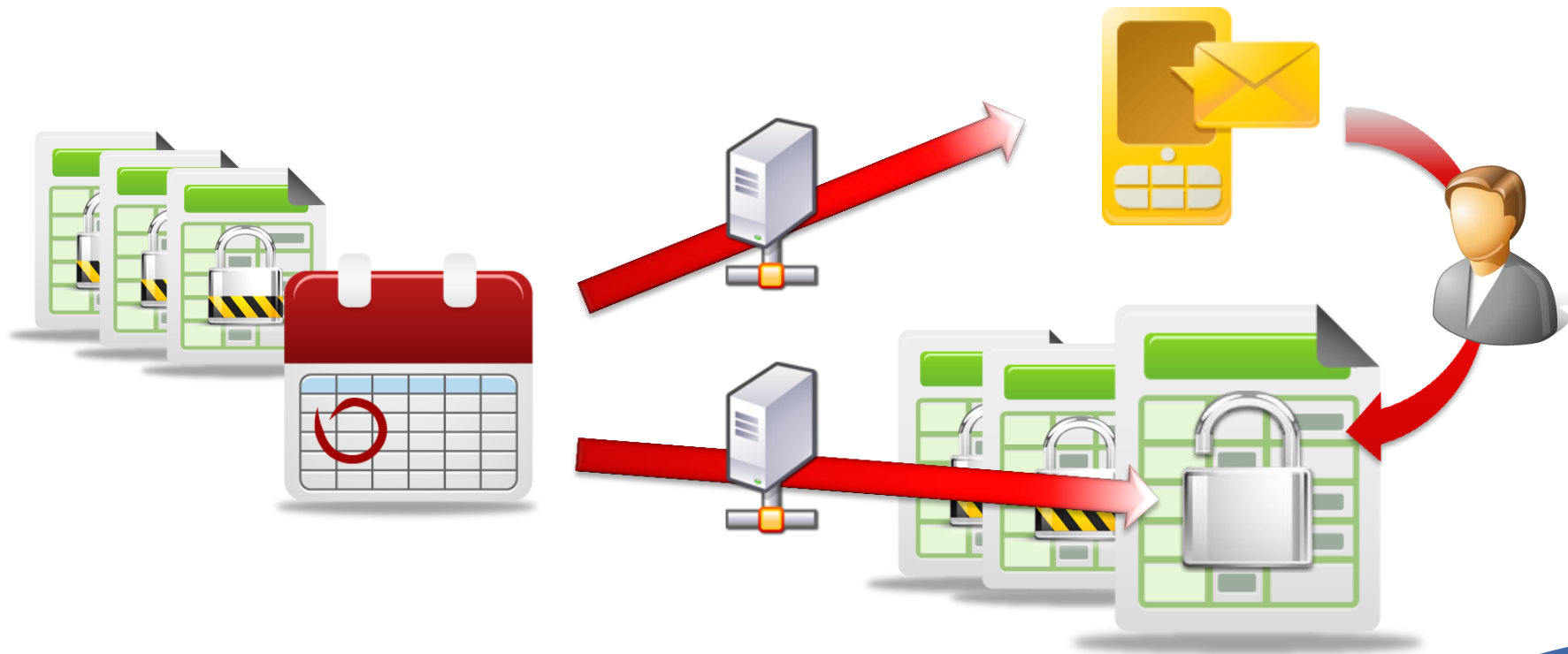




## Security and authentication

Enhanced compliance with protocol timeline

**PIN codes are only valid during a pre-defined time window (according to the protocol) and renewed for each questionnaire**







## Enhanced data Quality

- ✓ Fully time stamped data entry
- ✓ Full online audit trail
- ✓ Edit checks, dynamic behaviors
- ✓ Advanced graphic data entry fields
- ✓ Ease of use for patients / subjects

The screenshot displays the 'CleanWeb - Study Designer' interface for 'Score ASIA'. It features a central anatomical diagram of a human body with spinal segments labeled (C2-C7, T1-T4, L1-L5, S1-S2). To the right, there is a 'Symétrie' (Symmetry) section with checkboxes for 'Droite' (Right) and 'Gauche' (Left) for various motor functions like 'Flexion du coude', 'Extension du poignet', etc. Below the diagram, there are radio buttons for 'Motricité' (Motor) with options: 'Parésie totale', 'Contraction palpable ou visible', 'Mouvement actif, en absence de pesanteur', 'Mouvement actif, contre pesanteur', 'Mouvement actif, contre légère résistance', 'Mouvement actif, contre résistance complète', and 'Non évaluable'. At the bottom, there is a section titled 'Évaluation de la douleur' (Pain evaluation) with a sub-section 'ÉVALUATION SUR LES DERNIÈRES 48H' (Evaluation in the last 48h). It includes two horizontal sliders for 'Douleur dans le dos' (Back pain) and 'Douleur dans les jambes' (Leg pain), both ranging from 'Aucune douleur' (0) to 'Douleur insupportable' (100). The interface includes 'Enregistrer' (Save) and 'Vérifier' (Check) buttons.



## Automated reminders

Patients' / Subjects' compliance induction

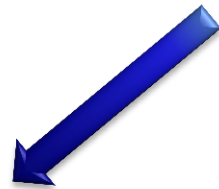
Automated reminders (**SMS, emails ...**) can be configured at specified time points before, during or ... after data entry time windows





## Versatility of entry means

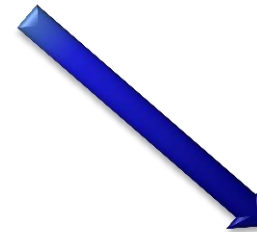
“Responsive design” featured



Personal computer



Smartphone



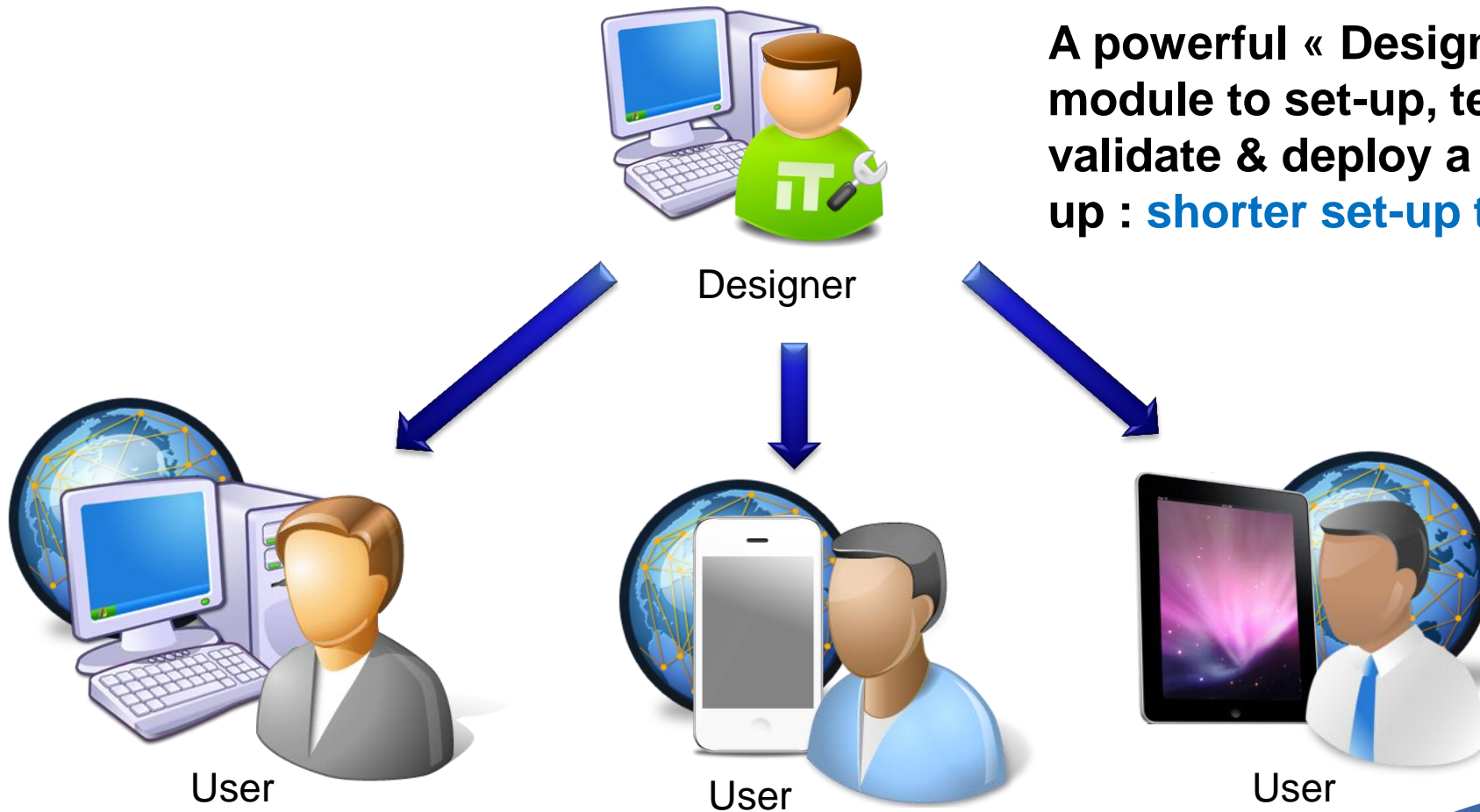
Tablet PC



## Flexibility – adaptability

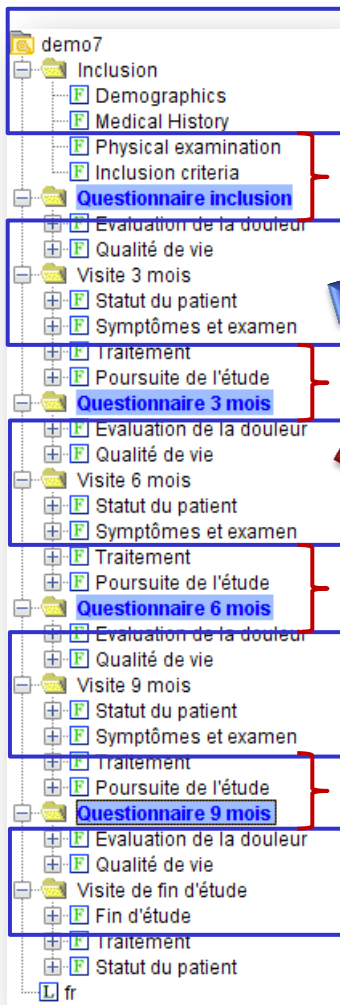
Upgrades available immediately : a 1 click process

A powerful « Designer » module to set-up, test, validate & deploy a full set-up : **shorter set-up time**



## Full integration with eCRF

Optimized processes – no “mapping” issues







## Powerful real time monitoring boards

Optimize project team resources, automated reports

Patients Nouveau Patient Queries Planning Exporter

Désactiver les alertes Commentaire

Type Statut Référence patient Centre Investigateur

Référence patient	Type	Date théorique	Date effectuée	Statut	Commentaire
01-001	4 - Visite J90	19/05/2013		A venir	
01-003	4 - Visite J90	12/05/2012		Non rempli	
01-004	4 - Visite J90	19/05/2013		A venir	
01-005	4 - Visite J90	19/05/2013		A venir	
01-006	4 - Visite J90	07/04/2013		Non rempli	
01-007	4 - Visite J90	09/01/2013		Non rempli	
01-008	3 - Visite J30	11/05/2013		A venir	
01-009	3 - Visite J30	11/05/2013		A venir	
01-010	3 - Visite J30	11/05/2013		A venir	
01-011	3 - Visite J30	11/05/2013		A venir	
01-013	3 - Visite J30	14/05/2013		A venir	
01-014	2 - J10	26/04/2013		A remplir	
01-015	3 - Visite J30	17/05/2013		A venir	
01-016	2 - J10	25/04/2013		A venir	
01-017	2 - J10	26/04/2013		A remplir	
01-018	2 - J10	01/05/2013		A remplir	
01-019	4 - Visite J90	13/06/2012		A venir	
03-001	3 - Visite J30	08/05/2013		A venir	

View by « event »

Patients Nouveau Patient Queries Planning Exporter

Désactiver les alertes Commentaire

Type Statut Référence patient Centre Investigateur

01-018

Référence patient	Type	Date théorique	Date effectuée	Statut	Commentaire
01-018	1 - Inclusion		21/04/2013	Rempli	
01-018	2 - J10	01/05/2013		A remplir	
01-018	3 - Visite J30	21/05/2013		A venir	
01-018	4 - Visite J90	20/07/2013		A venir	

View by patient



## To summarize ...

- **Ease of use by patients & project teams**
- **Increased data quality** (authentication, time stamp, enhanced date entry I/F ...)
- **Additional privacy for patients / subjects**
- **Powerful compliance induction features** (automated reminders...)
- **Dramatic cost savings** (*no hardware , no maintenance, no logistics...*)
- **Flexibility / adaptability** (long term studies ...)
- **Adapted for large populations**
- **Efficient real time monitoring & reporting tools**
- **Point of concern :**
  - Internet connection required,
  - Population bias ?





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**Thank you for your attention !**



telemetric  
technologies