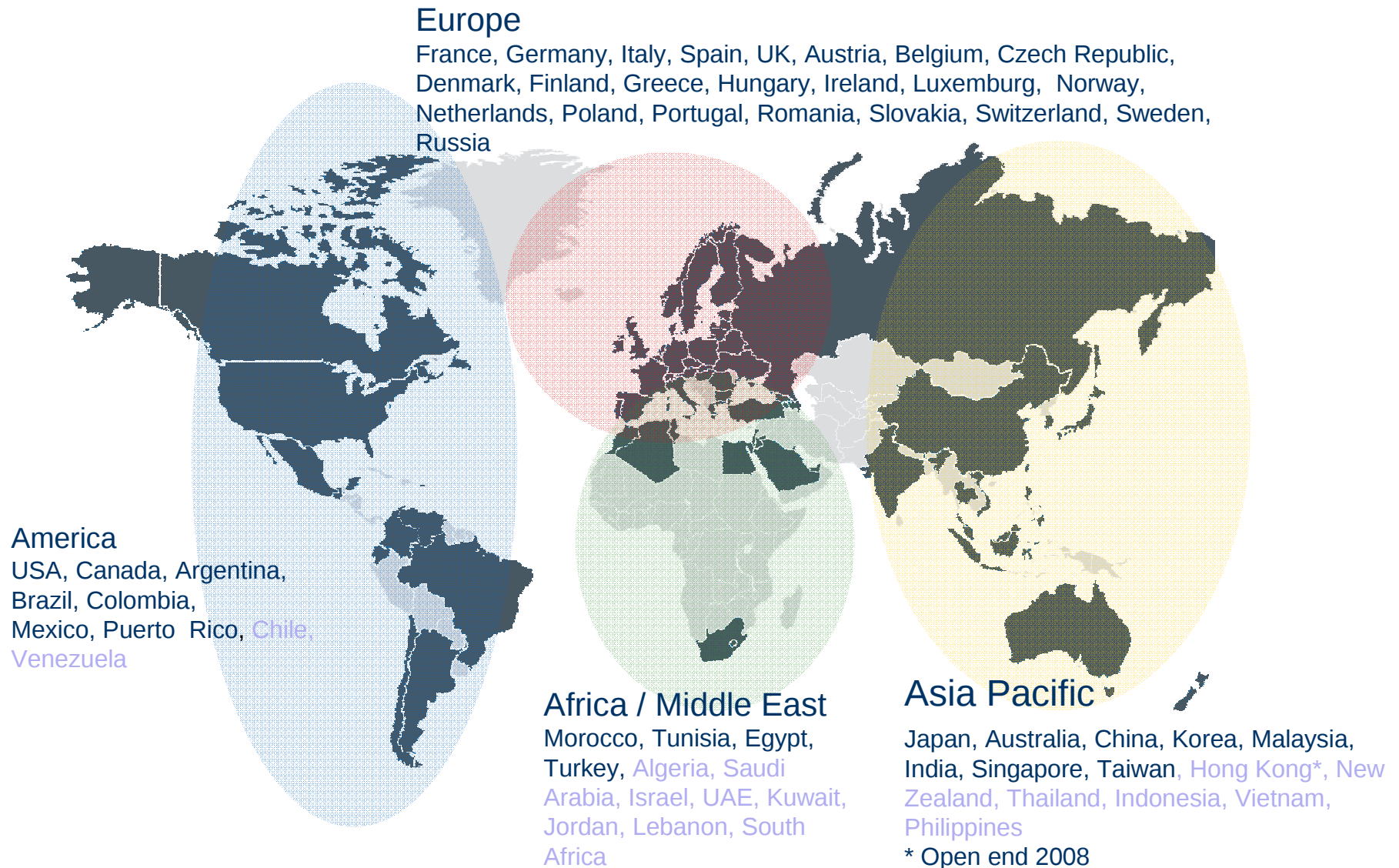
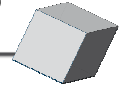


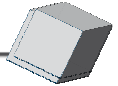


International Activities and Real life Patient data

CSD COVERAGE: 58 COUNTRIES



INTERNATIONAL EXPERTISE



HQ TEAM

**INTERNATIONAL
MANAGER**

Based in France, Paris

**MEDICAL
DIRECTOR**

Based in France, Paris

**STRATEGIC ALLIANCE
MANAGER**

Based in UK, London

LOCAL TEAM

FRANCE

26 people

Doctors,
Pharmacists,
Biostatisticians,
Data manager,
Programmer,
Project Manager,
CRA,
Research Analysts,
Medical writer

UK (CSD EPIC)

16 people

Pharmacists,
Health Economist
Epidemiologists
Research
Analysts,
Statisticians,
Programmers

ITALY

3 people

Epidemiologist,
Doctor, Research
Analyst

GERMANY

**Local CSD
representative**

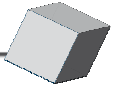
SPAIN

**Local CSD
representative**

US

1 Person

Local représentative in BELGIUM, INDIA, CHINA, JAPAN



**Epidemiological & Economic in hospitals & amongst office-based GPs
for **Pharmaceutical Companies, Institutions & Associations****

Observational studies

- ✓ Using existing longitudinal patient databases (LPD) amongst office-based physicians
- ✓ Using customised data collection through INES® in hospital & amongst office-based physicians



- ✓ Pharmaco-epidemiology studies
- ✓ Risk management & drug safety studies
- ✓ Health Economics and Outcomes studies
- ✓ Drug Utilisation studies

MEDICAL RESEARCH COLLECTION METHODS

A

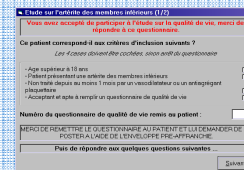


PATIENT DATA
THROUGH PRACTICE
SOFTWARE (LPD)

B



PATIENT
DATA
THROUGH
LPD



EXTRA
INFORMATION
VIA SPECIAL
SCREEN



PATIENT
QUESTION
NAIRE

C



CRF
ONLINE
VIA INES



PATIENT
QUESTIONNAIRE



Practice Management Software available in France, Italy, UK, Germany, Belgium, Australia, Czech Republic, Korea & Spain



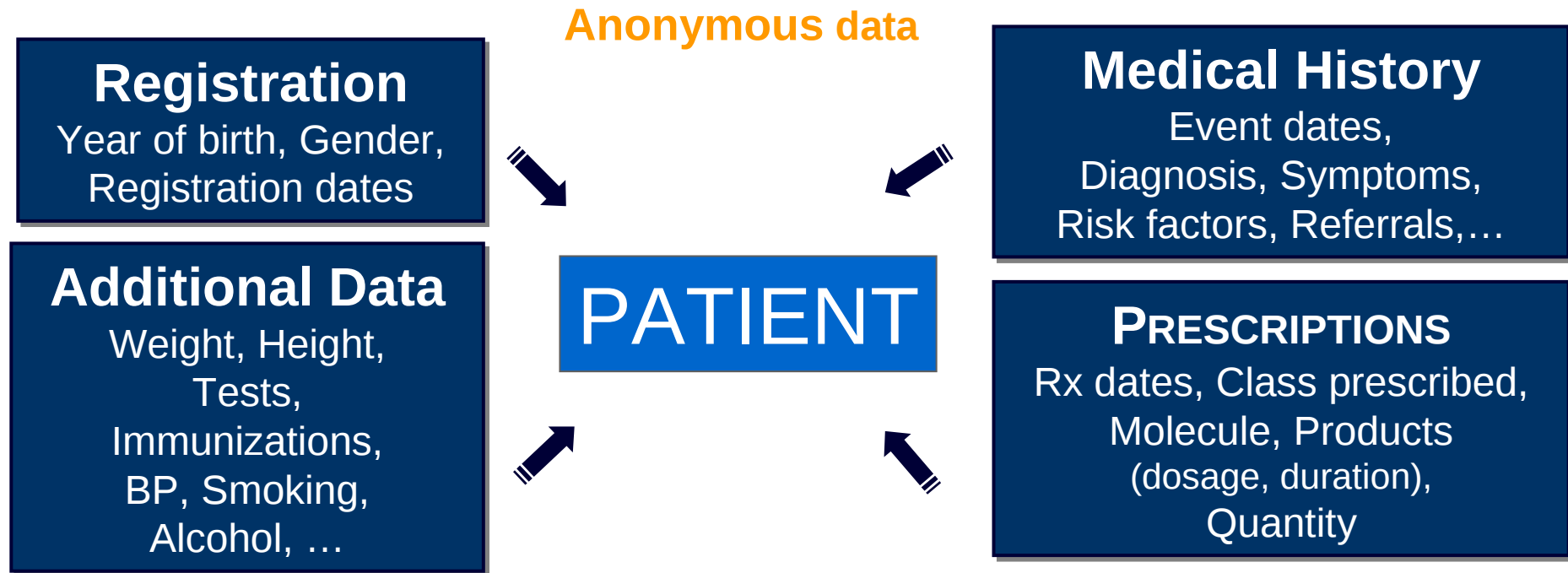
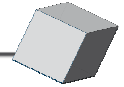
Online or paper CRF available worldwide

LONGITUDINAL PATIENT DATABASES (LPD): METHODOLOGY

CSD Medical Research works with Longitudinal Patient Databases LPD

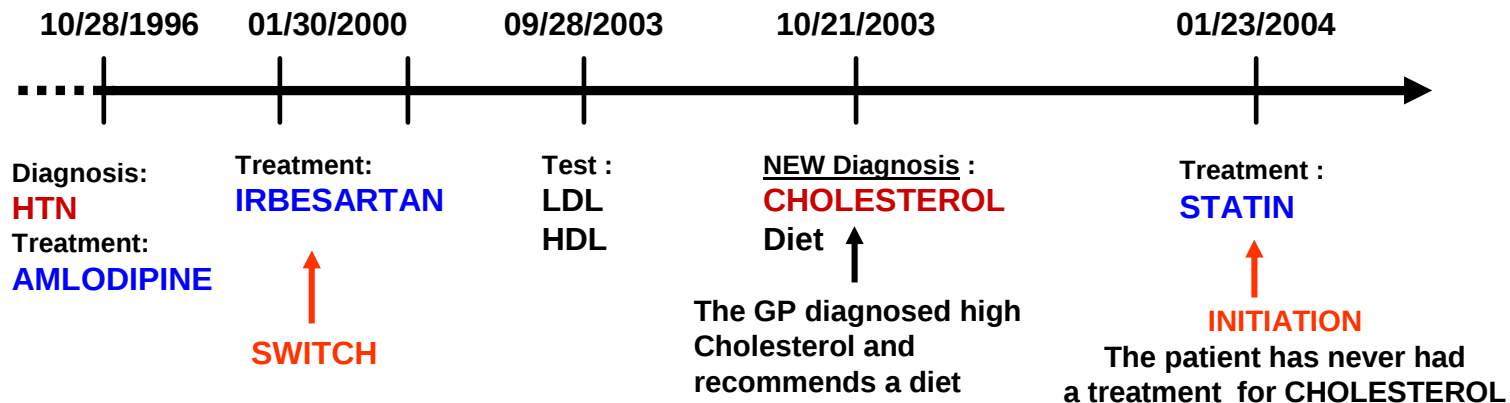


WHAT PATIENT DATA DO WE COLLECT ?



Example

PATIENT FOLLOW-UP



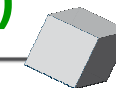
PROPRIETARY DATABASE : COVERAGE

CSD owns 9 Longitudinal Patient Databases



	Countries	# of Physicians	# of Active Patients
	France	1200 GPs, 800 Spec	2,600,000 patients
	UK	382 practices	2,900,000 patients*
	Italy	700 GPs	800,000 patients
	Germany	500 GPs	590,000 patients
	Belgium	300 GPs	300,000 patients
	Australia	250 GPs	330,000 patients
	Czech Republic	100 GPs	120,000 patients
	Spain	Launched in 2008	* All patients presenting in the last year except UK, all patients registered
	Korea	Launched in 2008	
CSD with Partner:	USA	All GPs, All Spes	50,000,000

COMPARISON : COLLECTED DATA & KEY FIGURES (1/2)



PATIENT DATA

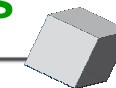
Countries	France	UK	Italy	Germany	Belgium
Patient data					
Gender	YES	YES	YES	YES	YES
Year of birth	YES	YES	YES	YES	YES
Socio and economic status	YES	YES	NO	NO	YES
Ethnicity	NO	NO	NO	NO	NO
Death recording	NO	YES	PARTIAL	NO	NO
Weight	YES	YES	YES	YES	YES
Height	YES	YES	YES	YES	YES
Blood pressure levels (systolic/diastolic)	YES	YES	YES	YES	YES
Dates of events (consultation)	YES	YES	YES	YES	YES
Home visit	YES	YES	YES	NO	YES
Risk factors : Allergies, diabetes, HTN, tobacco, alcohol...	YES	YES	YES	YES	YES
Medical history	YES	YES	YES	YES	YES
Diet	PARTIAL	PARTIAL	PARTIAL	NO	PARTIAL
Exercise	NO	PARTIAL	PARTIAL	NO	PARTIAL
Lifestyle	NO	PARTIAL	PARTIAL	NO	PARTIAL

COLLECTED DATA & KEY FIGURES (2/2)

PRESCRIPTION AND ADDITIONAL HEALTH DATA

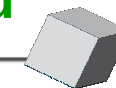
Countries Prescription data	France 	UK 	Italy 	Germany 	Belgium 
Diagnosis	YES	YES	YES	YES	YES
Drugs	YES	YES	YES	YES	YES
Duration of script	YES	YES	YES	YES	YES
Dosage	YES	YES	YES	YES	YES
Cost (unit)	YES	NO	YES	YES	YES
Reimbursement	YES	NO	YES	YES	YES
Generic name	YES	YES	YES	YES	YES
Prescription by brand name	YES	NO	YES	YES	YES
Prescription by molecule	NO	YES	YES	NO	NO
Repeat	YES	YES	YES	YES	YES
Lab and X-ray exams	YES	YES	YES	YES	YES
Results	YES	YES	YES	YES	YES
Referrals to specialist	PARTIAL	YES	PARTIAL	PARTIAL	PARTIAL
Hospitalizations	NO	YES	PARTIAL	PARTIAL	NO

Comparison of Databases: Applications experience and publications



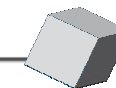
Countries	France 	UK 	Italy 	Germany 	Belgium 
Main Applications	Drug utilization Cost and Resource studies Compliance Persistence Incidence Prevalence	Epidemiology and drug safety Health Economics and Outcomes Drug utilisation	Drug utilization Cost and resource studies Some epidemiology and drug safety Compliance Persistence Incidence Prevalence	Drug Utilisations other applications being evaluated	As France
Validation	Internal and external	Internal and external	Internal and external	Internal	Internal
Publications	widely Academic and Industry	widely Academic and industry	Some publications	pending	pending
Used by health and regulatory authorities	yes	yes			
Additional screen and questionnaires possible	Yes and studies been completed	Yes and studies been completed	possible	Being evaluated	possible
Data extraction Access to Dataset	yes	yes	yes	yes	yes
Complete dataset under license	No	yes	No	No	No

Comparison of Coding systems used



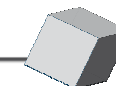
Countries Coding system	France 	UK 	Italy 	Germany 	Belgium 
Drug code Dictionary	Claude Bernard	Multilex	Farmadati	Abdata	Delphi & Tarif
Therapeutic classification	EphMRA* Mapped to ATC	BNF	ATC	ATC	ATC
Signs, Symptoms, Diagnoses, Investigations	Home grown thesaurus Mapped to ICD-10	Read codes	ICD-9	ICD-10	Home grown thesaurus + ICD-10 + ICPC

PLD DB: Patients with chronic diseases



Paesi Chronic disease	France 	UK 	Italy 	Germany 	Belgium 
Asthma	51,000	121,600	32,400	39,300	12,500
COPD	39,000	20,400	15,300	37,300	10,800
Hypertension	230,000	246,000	144,000	175,000	48,200
CHD	38,000	66,000	26,000	39,900	7,000
Dyslipidemia	160,000	185,000	53,000	89,900	27,700
Diabetes	57,000	77,000	36,500	64,800	10,400
Chronic Heart failure	16,000	13,000	7,800	21,300	2,700
Stroke	13,000	21,500	11,500	24,600	1,500

Example 1



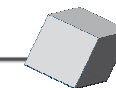
Studio realizzato nel 2004: l'associazione di almeno tre fattori di rischio si trova nell'11% dei pazienti ipertesi senza precedenti episodi di coronaropatie.

Prevalenza di ipertesi per numero di fattori di rischio associato in Francia - Anno 2004		
Totale pazienti con IA	10 262 242	100%
Pazienti ipertesi con precedenti episodi di coronaropatie	944 126	9,2 %
Pazienti ipertesi in prevenzione primaria	9 318 116	90,8%
Pazienti senza altri fattori di rischio	1 067 273	10,4 %
Pazienti con 1 fattore di rischio	4 094 635	39.9 %
Pazienti con 2 fattori di rischio	3 037 623	29.6 %
Pazienti con 3 fattori di rischio e +	1 128 847	11,0 %

Tenendo conto di questi dati, e stimando la popolazione ipertesa in Francia nell'ordine di 8 milioni, il numero totale di pazienti ipertesi che presentano 3 fattori di rischio si stima essere 2 000 000.

La prevalenza reale dell'ipertensione potrebbe essere superiore a quella dell'ipertensione diagnosticata o trattata. Questa sarebbe stimabile in 12,5 - 14,2 milioni di individui.

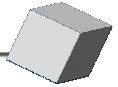
ASTHMA & COPD



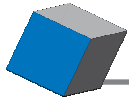
Basis : Patients having received at least one prescription per period

	YEAR 2006	YEAR 2007
TOTAL PATIENTS ANTI-ASTHMATIC	15.150	14.504
TOTAL PATIENTS IN THE CONTROLLER MARKET	11.608	12.175
ANTICHOLINERGICS	6.554	6.080
ANTILEUCOTRIENS	298	303
LABA	1.731	1.600
ICS	5.411	5.659
FIXED COMBINATION	5.141	6.040
TOTAL PATIENTS in short term treatment	7.345	6.890
ANTI INFL RESP	158	134
SABA	2.524	2.984
FIXED COMBINATION (SABA+ICS)	1.079	899
XANTHINES	4.635	3.985

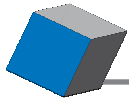
Tables to be produced on patients with diagnosis of BPCO and on patients with diagnosis of ASTHMA (2 separate sets of tables). MAT 2006/2007



In the LPD Database LPD in year 2007



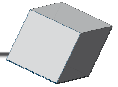
OAD Prescriptions



At least one HbA1c value registered in the year

9500 REAL patients

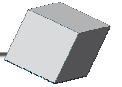
To build the study



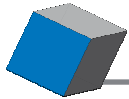
Patients clustering

- Type II diabetes
- undergone to OAD therapy for at least 6 mths
- with or without insulin
- followed by GPs in Italy
- other risk factors

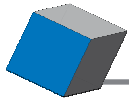
**Reaching the therapeutic objective of
glycaemia control: HbA1c on target**



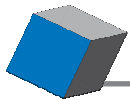
Examine the relationship between pts characteristics and glycaemia control



demographic characteristics



Pts risk factors



Therapeutic schemes (mono therapy, bi-therapy, three-therapy, insulin-therapy)

MEDICAL RESEARCH COLLECTION METHODS

A

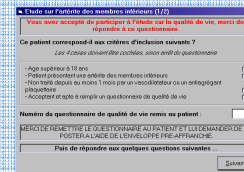


PATIENT DATA
THROUGH PRACTICE
SOFTWARE (LPD)

B



PATIENT
DATA
THROUGH
LPD



EXTRA
INFORMATION
VIA SPECIAL
SCREEN



PATIENT
QUESTIONNAIRE

C



CRF
ONLINE
VIA INES



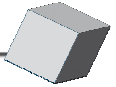
PATIENT
QUESTIONNAIRE

A B

Practice Management Software available in France, Italy, UK, Germany, Belgium, Australia, Czech Republic, Korea & Spain

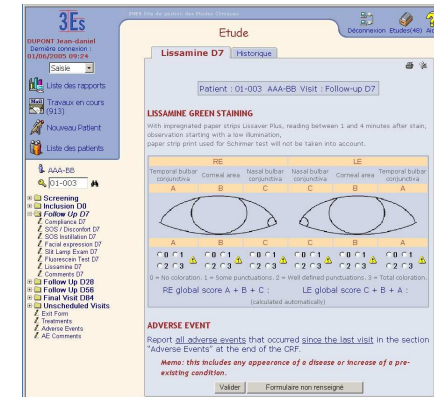
C

Online or paper CRF available worldwide



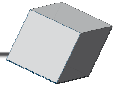
What is INES © Software?

- 100% web (no installation required)
- User friendly interface
- Customized task checklist on home page
- On line completion guidelines
- Online Data Management
 - ✓ Automatic Data Clarification Forms (DCF)
 - ✓ MedDRA and WHODrug coding
- Compliant with 21 CFR Part 11
- Can be combined with the Electronic Medical Record, as stand alone or with paper questionnaires



The screenshot displays the INES software interface. On the left is a sidebar with a navigation menu including options like 'Accueil', 'Liste des rapports', 'Travaux en cours', 'Nouveau Patient', and 'Liste des patients'. The main area shows a patient record for 'Lissamine D7' with a 'Historique' tab. Below this, there's a section for 'LISSAMINE GREEN STAINING' with instructions and a form for recording results. The form includes columns for 'RE' and 'LE' (Right and Left eyes) with sub-columns for 'Temporal bulbar conjunctiva', 'Corneal area', 'Nasal bulbar conjunctiva', and 'Corneal area'. There are also fields for 'Global score A + B + C' and 'Global score C + B + A'. At the bottom, there's an 'ADVERSE EVENT' section with a text area for reporting events and buttons for 'Valider' and 'Formulaire non renseigné'.

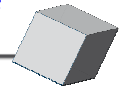
Ideal for accessing specialists or additional information not available through existing patient databases



 Advantages :

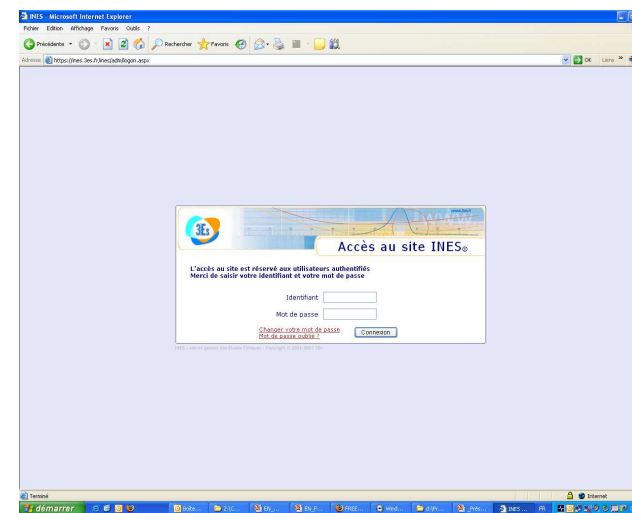
DOCTOR RELATIONSHIP MANAGEMENT

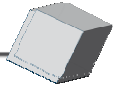
- Integrates quotas and representativity criteria
- Pre selection of doctors from Onekey Pharbase references
- Dynamic balance of doctor quotas during recruitment
- Contacts management and follow up:
 - ✓ Automatic notification emails
 - ✓ Contacts history and details
 - ✓ Call-back schedules
- Fee Management



Transparency

- Online up-to-date data
- Dashboard: inclusion curve, automatic reports preparation, custom-made analyses and graphics according to the project milestones





Longitudinal International Patient Study on Awareness of abdominal adiposity

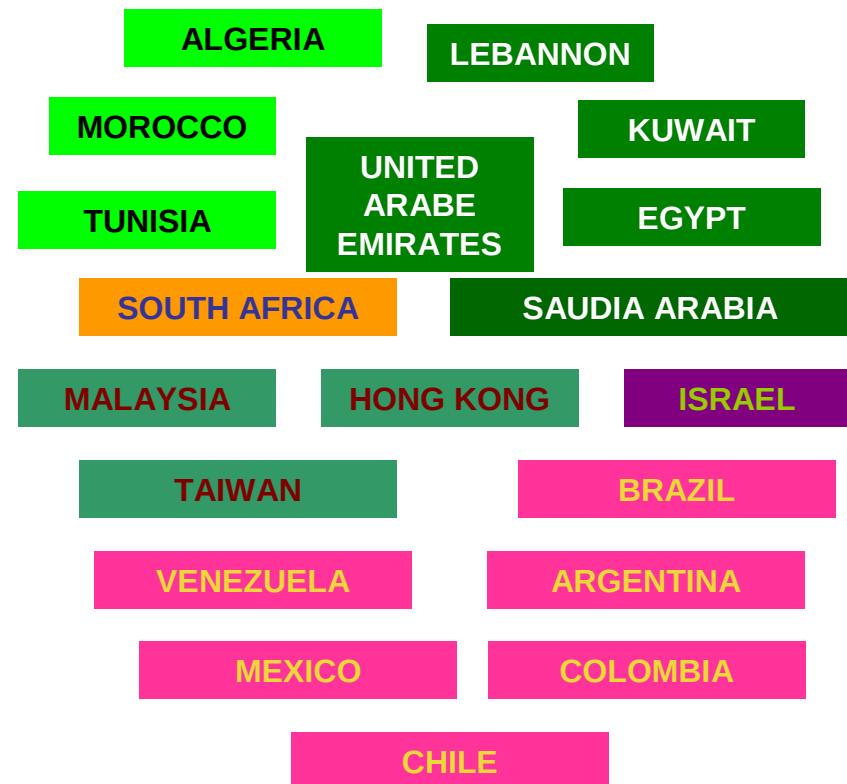
METHODOLOGY

Study covers 19 countries

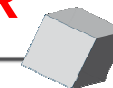
In-house fieldwork by CSD local teams

400-1200 patients included by country
Telephone interviews of the same patients
T, T+3, T+6, T+9 months

More than 80% of the patients studied
answered all 4 questionnaires



Conclusions: CSD MEDICAL RESEARCH: OFFER



Therapeutic areas covered in Hospitals and private medicine (GPs and Specialists) :

- Biomedical Research
- Epidemiological Studies
- Observational Studies

PRE-REGISTRATION

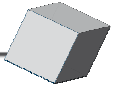
EPIDEMIOLOGICAL STUDIES

- Prevalence
- Incidence
- Target Populations
- Evaluation of the current care practices of a pathology
- Pharmaco-Epidemiology

POST-REGISTRATION

OBSERVATIONAL STUDIES

- Joined Population
- Drug Utilisation
- Persistence & Observance
- Regulatory Studies [HAS (France), Health Ministries (France & Italy), Universities (UK)]
- Post Marketing Studies
- Economic Studies



THANKS FOR YOUR ATTENTION!

