



STENTYS

Real-world data for post marketing
surveillance in eight European countries

ACDM Annual Conference 14th March Brussels

Contents

2

Stentys: The company

Medsharing: The provider

The Sizing registry

Lessons learned

Data security in the Cloud

Stentys : The company

3

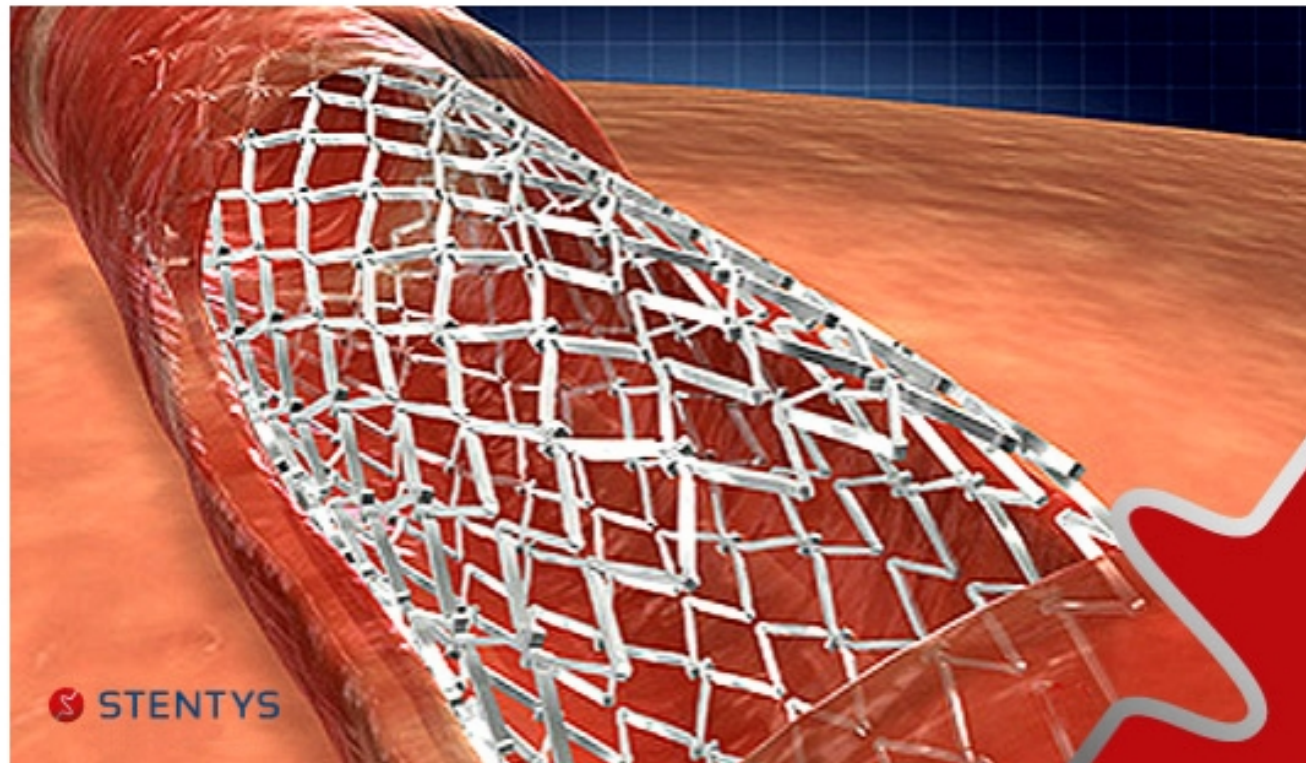
- ▶ www.stentys.com
- ▶ Mid-size medical device company
- ▶ Stents used in interventional cardiology
- ▶ Indications: Acute myocardial infarction / Complex coronary artery disease
- ▶ Founded in 2006
- ▶ HQ: Paris
- ▶ Employees: 42 in 10 countries
- ▶ Listed at Paris EuroNext stock exchange

Medsharing: The provider

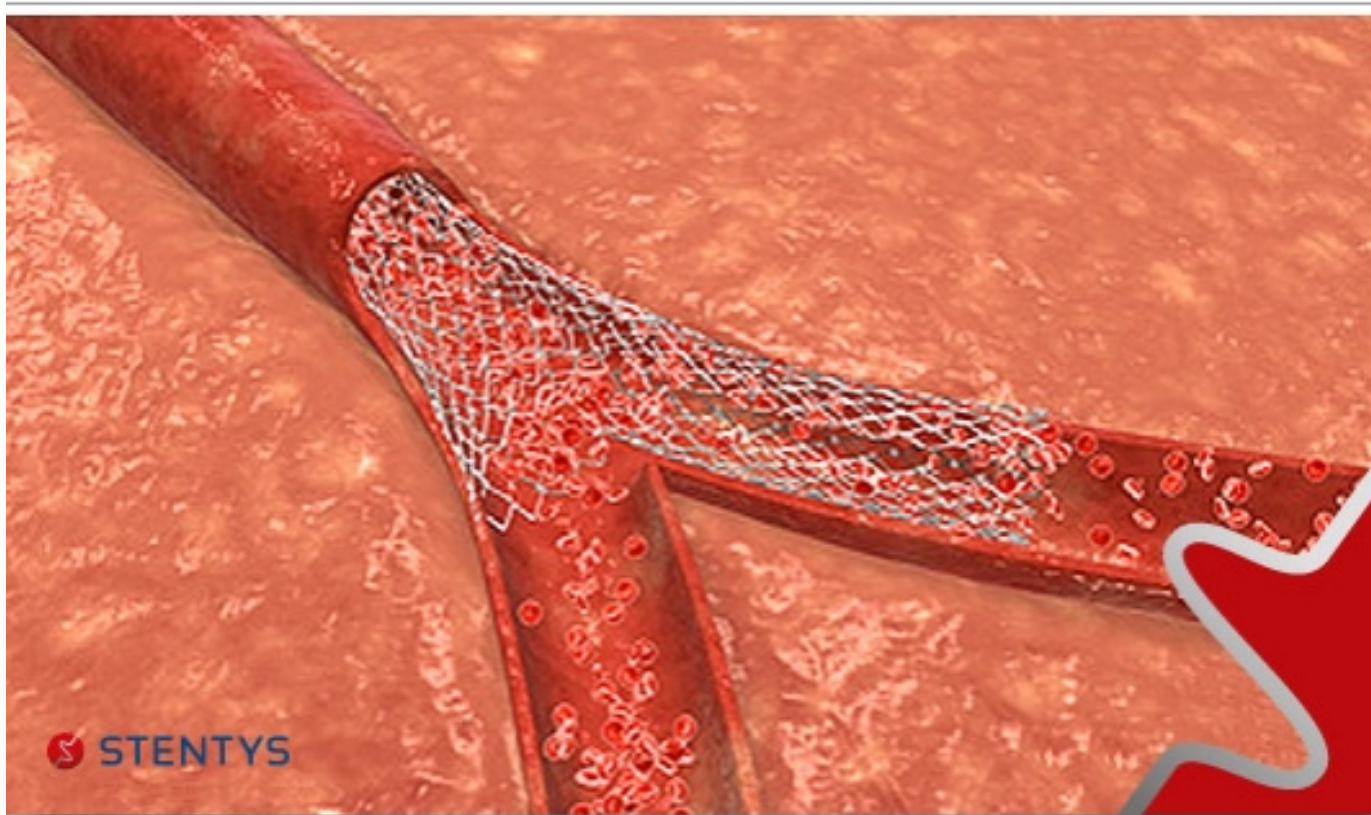
- ▶ eCRF Software provider 100% internet
- ▶ Created in 2000
- ▶ 160+ studies already done, 70+ actives
- ▶ 9 people
- ▶ 5 shareholders, among them a hospital surgeon, trial coordinator
- ▶ Healthcare compliant hosting
- ▶ ISO 9001:2008
- ▶ Compliant 21 CFR Part 11 and GAMP 5

Acute Myocardial Infarction (AMI)

5



Bifurcations



Stentys : The Sizing Registry

- ▶ Registry objectives:
 - ▶ Identify patient population in which the stents are used in routine practice
 - ▶ Record and monitor Major Adverse Cardiac Events (MACE)
 - ▶ Communicate easily with site investigators
 - ▶ Create community with investigators and CRAs at this occasion. Allow for secure private messaging.
 - ▶ Provide training of investigators,
 - ▶ Allow investigators and users to share experience with one another (forum) – case corner
- ▶ Goal: 3,000 patients

Stentys : The Sizing Registry

- ▶ Launched in 2012
- ▶ Live set-up in 3 months
- ▶ 2014: 42 sites, 700 patients included, 8 European countries
- ▶ 2017: 45 sites, 1260 patients included, 10 countries in Europe and Asia; 207 investigators
- ▶ Language: English

What was required to make the registry successful?

9

- ▶ A collaborative platform to **improve communication** between sponsor and sites
- ▶ **Optimised user experience** to increase adoption
- ▶ **Autonomy**: Stentys to extract data and create flexible reports themselves

What was implemented to make the registry 10 successful?

- ▶ **Portal for communication**
- ▶ **Optimised user experience:**
 - ▶ Interactive picture to identify coronary segments with coronary stenosis: a click instead typing words
 - ▶ Contextual blocs in the MACE data entry screen

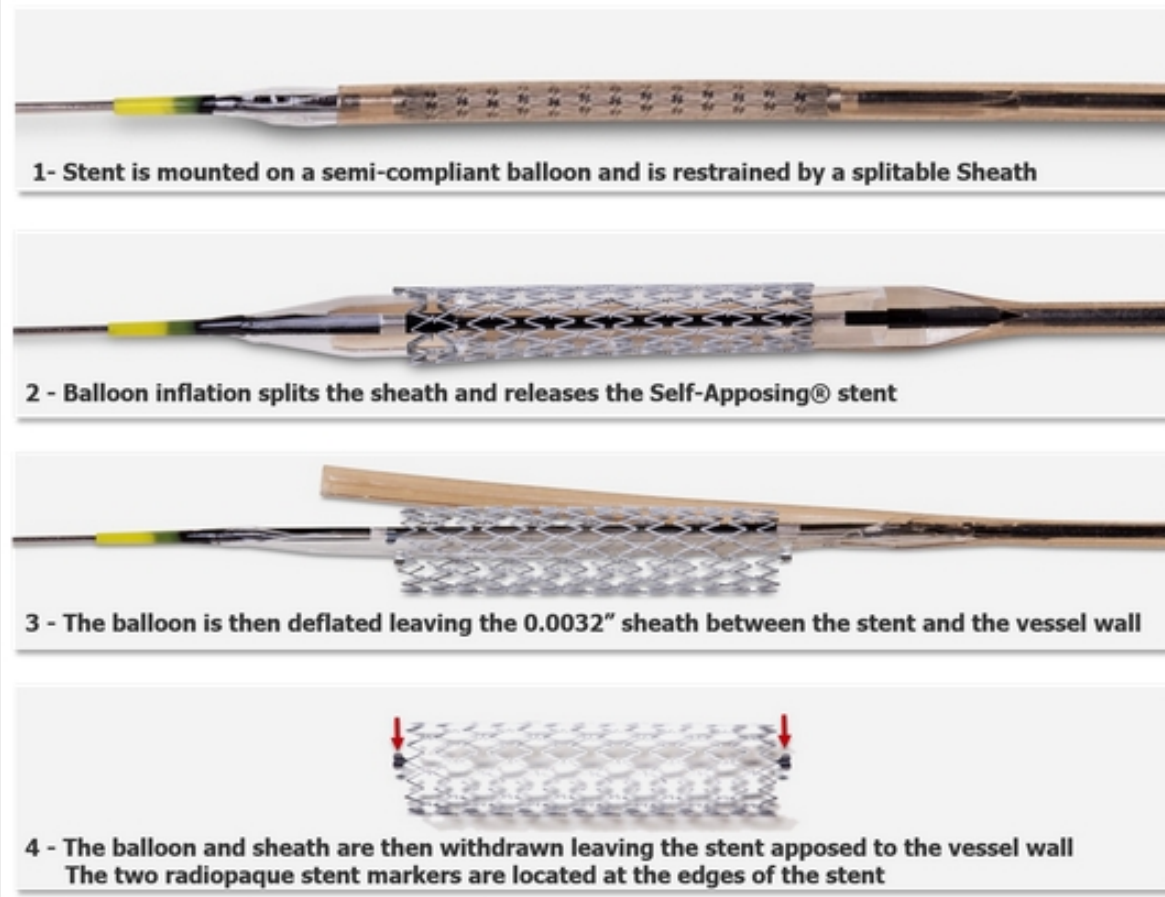
Lessons learned

- ▶ Workload to make the portal successful more important than expected
 - ▶ Stentys project manager had less available time than required
- ▶ Difficult to get medical doctors to share infos this way
- ▶ Interactive picture and contextual windows proved efficient to increase registry's adoption

Next steps

- ▶ Reach the target of 3000 patients
- ▶ New study launched in March – WW (excl. US): registry to assess the Stentys Xposition S for revascularization of coronary arteries in routine clinical practice
 - ▶ Also managed with eCRF EOL ©

Next steps





eCRF



NEWS

7 October 2013 - New left main case on STENTYS iPhone app by Prof. Holger Nef (Germany). Download the app now!

22 May 2013 - Further data on STENTYS self-apposing stent reinforces strength of clinical results

20 May 2013 - STENTYS enrolls first heart attack patient in pivotal U.S. clinical trial

09 March 2013 - STENTYS Self-Apposing® Stent Demonstrates Lowest Mortality Rate Among Large Heart Attack Trials

more news

UPCOMING EVENT TCT 2013



Date:
27 OCT - 1 NOV
2013
Location:
San Francisco, USA

CASE CORNER



- ACS
- Large Vessels
- Left Main
- Bifurcations
- Aneurysms
- SVGs

ASK THE EXPERT



Do you have a question for an expert STENTYS user? Would you like to share your experience with the STENTYS BMS or DES^(P) stent? **Please send your feedback to info@stentys.com and we will forward your request!**

RESOURCES

Videos

- STENTYS Animation
- STENTYS Training Video
- STENTYS Competitor Video

Slides

- APPOSITION III 1 year results in...
- STENTYS Clinical Message
- STENTYS Speaker Slides
- History of STENTYS STEMI Clinical...
- STENTYS stent images
- APPOSITION I and II - presented at...

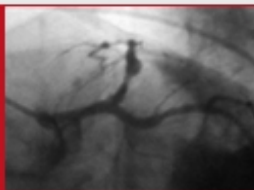
Documents

- Sizing Marketing Brochure
- STENTYS AC brochure 6F
- STENTYS Next Generation delivery...
- STENTYS Training Aid FINAL with...
- STENTYS Training Poster FINAL A2
- Sizing Registry Brochure

more resources


Coronary stenosis complicated by post-stenotic aneurysm

14 June 2012



Prof. C. Tamburino
Dr A. La Manna
Dr S. Geraci
University of Catania, Ferrarotto Hospital, Catania
ITALY

Male, 60 years old
- **Risk Factors:** Hypertensive, Dyslipidemic, Smoker.
- **Clinical Presentation:** Syncope.
- **Ecocardiography:** Hypokinesia of the antero-septal wall with moderate ejection fraction reduction (L.V.E.F. 48%).
- **SPECT:** Reversible anterior myocardial ischemia.

 [View Slides](#)

STEMI with aneurysm, 9 month OCT follow-up

14 June 2012





Dr Carmelo GRASSO
Dr Salvatore GERACI, MD
Prof. Corrado TAMBURINO
University of Catania, Ferrarotto Hospital, Catania
ITALY

Male Caucasian patient, 73 years old with hypertension
24 January 2011 >>> Anterior STEMI
Echocardiography: EF 45%. Apical akinesia. Ipokinesia of basal anterior wall

 [View Slides](#)

CASE CORNER

-  [ACS](#)
-  [Large Vessels](#)
-  [Left Main](#)
-  [Bifurcations](#)
-  [Aneurysms](#)
-  [SVGs](#)

[sizing platform](#)

STENTYS Sizing Registry

INCLUSION NO.0001

[«Return to Menu](#)

[«Return to the list of cases](#)

[«Return to Case](#)

[«Disconnect](#)

The Patient	Investigator
Subject ID: FR_001-001 Gender: Male Date of Input: 11/04/2012	Name: Dr Paul Martin Centre No.: 1

[Amendments history](#) [Full print out of Case Report Form](#)

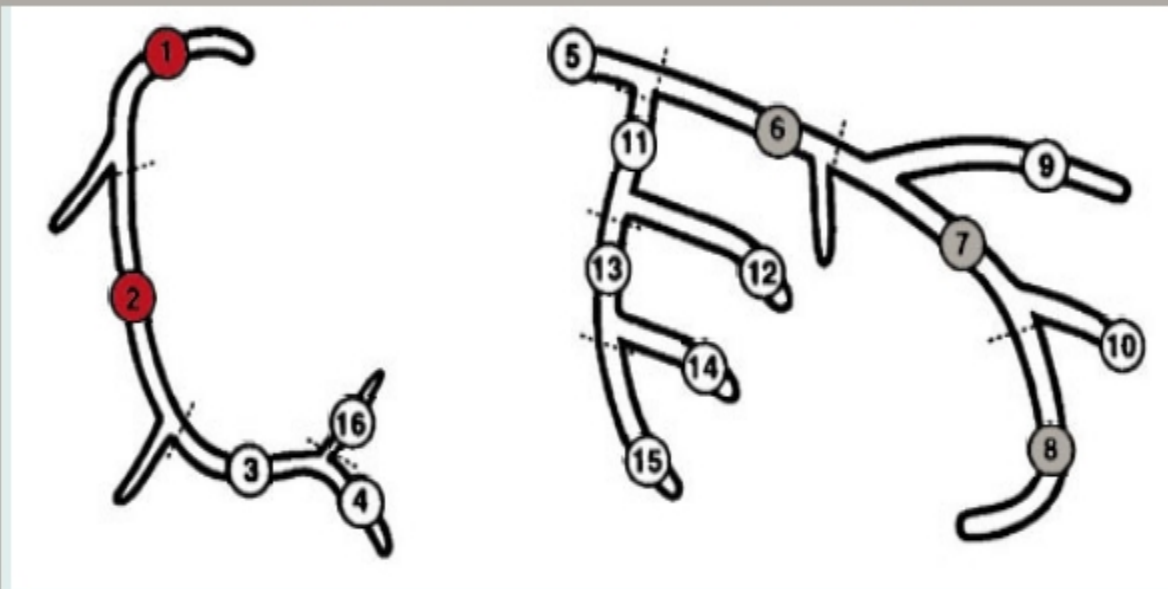
[Help](#)

CASE REPORT FORM							
Questionnaires	Date of visit	% data captured	Validated		Correction request		Print
			Investigator	Monitor	Monitor	System	
BASELINE / PROCEDURE / MEDICATION BEFORE & DURING PROCEDURE							
PROCEDURE	05/08/2012	85	Not validated Validate ?	Not validated	0	0	Print
AFTER PROCEDURE / AT DISCHARGE							
MEDICATION		0	Not validated Validate ?	Not validated	0	0	Print
FOLLOW-UP (UP TO 12 MONTHS)							
FOLLOW-UP n°1		0	Not validated Validate ?	Not validated	0	0	Print
END OF STUDY		0	Not validated Validate ?	Not validated	0	0	Print
ADDITIONAL FORMS							
MAJOR ADVERSE CARDIAC EVENT FORM...							
DEVICE MALFUNCTION FORM n°1		0	Not validated Validate ?	Not validated	0	0	Print

[«RETURN](#)

ANGIOGRAPHIC PROCEDURAL INFORMATION

Identification of coronary segment(s) with significant stenosis ($\geq 50\%$ DS) at previous and/or current angiography.



Help

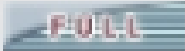



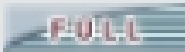

- * If you click once on segment, the bubble will turn red, meaning there is a significant stenosis in this segment.
- * If you click twice, the bubble will turn grey, meaning you have no information regarding this segment.
- * If you click a third time, the bubble will turn white, meaning there is no significant stenosis in the segment

You can also click directly on the questions below

1 - Prox RCA	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="checkbox"/> Unknown (Q78064)
2 - Mid RCA	<input checked="" type="radio"/> Yes <input type="radio"/> No <input type="checkbox"/> Unknown (Q78065)
3 - Distal RCA	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="checkbox"/> Unknown (Q78066)
4 - Right posterior descending	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="checkbox"/> Unknown (Q78067)
5 - Left main	<input type="radio"/> Yes <input checked="" type="radio"/> No <input type="checkbox"/> Unknown (Q78068)
6 - Prox LAD	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="checkbox"/> Unknown (Q78069)
7 - Mid LAD	<input type="radio"/> Yes <input type="radio"/> No <input checked="" type="checkbox"/> Unknown (Q78070)

MAJOR ADVERSE CARDIAC EVENT FORM







[Help](#)


MACE	MACE TYPE	Relationship to STENTYS product	% data captured	Validated		Correction request		Print
				Investigator	Monitor	Monitor	System	
MACE n°1	Emergent CABG	Yes		Not validated Validate ?	Not validated	0	0	Print
MACE n°2	(Re)-Myocardial Infarction	Probable		Not validated Validate ?	Not validated	0	0	Print
MACE n°3	Emergent CABG	Probable		Not validated Validate ?	Not validated	0	0	Print
MACE n°4	Revascularization/PCI	Unknown		Not validated Validate ?	Not validated	0	0	Print
MACE n°5	Occlusion / Stent thrombosis	Yes		Not validated Validate ?	Not validated	0	0	Print
MACE n°6	Death	Possible		Not validated Validate ?	Not validated	0	0	Print
Add new mace...								



[RETURN](#)

MACE n°5

MAJOR ADVERSE
CARDIAC EVENT FORM»[Send a message to the monitor»](#)[«Return](#)

-  System correction request
-  Monitor correction request
-  Data validated
-  Document attached
-  Help with the data
-  Data from preview visit

MAJOR ADVERSE CARDIAC EVENT FORM**MACE TYPE** Occlusion / Stent thrombosis (Q74841) Please complete the Occlusion Form below**OCCUSION/STENT THROMBOSIS FORM**

Date of occlusion/stent thrombosis	15/08/2013 (dd/mm/yyyy) (Q75114)
Occlusion/Stent thrombosis occurred	24 hours- 30 days post stent implantation (Q75115)
Was there evidence of stent thrombosis	<input checked="" type="radio"/> Yes <input type="radio"/> No (Q75116)
if yes,	please specify angiographic evidence (Q75117)
Occlusion in segment number	11 - Prox Cx (Q75118) <input type="checkbox"/> Unknown
Emergency bypass surgery (CABG)	<input checked="" type="radio"/> Yes <input type="radio"/> No (Q75120)
if yes,	 Please complete CABG Form below
Revascularization	<input checked="" type="radio"/> Yes <input type="radio"/> No (Q75122)
if yes,	 Please complete Revascularization Form below
Thrombolysis (i.c.,i.v.)	<input type="radio"/> Yes <input checked="" type="radio"/> No (Q75124)
GP IIb/IIIa receptor blockers	<input type="radio"/> Yes <input checked="" type="radio"/> No (Q75125)
Other therapeutic intervention	<input checked="" type="radio"/> Yes <input type="radio"/> No (Q75126)
if yes,	specify SPECIFY DE OTHER THERAPEUTIC INTERVENTINO characters (500 max) (Q75127) 41

How was data security handled in the Cloud?

20



SaaS: Software as a Service

How was data security handled in the Cloud?

- ▶ Need to comply with regulations and guidances, which exist at different levels: EU, country, industry
 - ▶ [EU data protection](#) rules of Jan 2012, published on 4 May 2016 and to be applicable to all EU companies starting 25 May 2018
 - ▶ Will extend a part of obligations to sub-contractors of data handling (e.g. hosting companies) (source: AFCROs eHealth workshop, Jan 2017)
 - ▶ Local country laws
 - ▶ Industry guidances; [FDA 21 CFR](#): *Open system* means an environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.
 - ▶ [ICH E6](#): The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
- ▶ Need to protect data against stealing, fraud or hacking

How was data security handled in the Cloud?

22

Logical access and network

- ▶ Connection to reserved access spaces with login/password
- ▶ Data security: Authentication by password and electronic signature based on defined access rights
- ▶ The information flowing between the investigator's client workstation and the server are encrypted in SSL 256 bits by RSA public/private key of 2048 bits and certified by a GlobalSign OrganisationSSL certificate.

How was data security handled in the Cloud?

23

Physical operation and safety

- ▶ Secured data storage: the data stored on servers are duplicated in real time on several disks
- ▶ High availability technical architecture (redundant servers and data)
- ▶ Data back-up strategy: Encrypted Back-ups on 2 sites in the same country by hosting company, daily incremental, complete weekly, complete monthly
- ▶ Physical access to premises: double entrance door controlled by a HandKey bio-metric player and camera systems. Server anonymity

Questions?

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