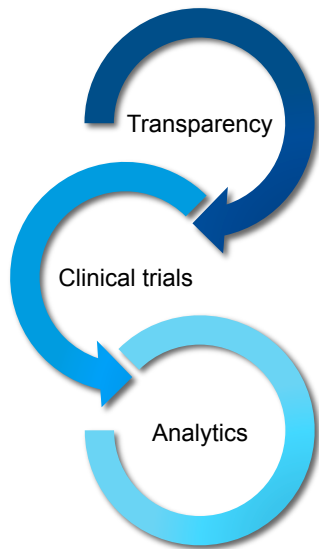


IMPROVING TRANSPARENCY OF CLINICAL DATA USING ANALYTICS

MARK LAMBRECHT, SAS



CONTENTS



- Transparency in clinical development
- Data transparency
- Analytics

TRANSPARENCY

trans·par·ent  *adjective* \tran(t)s-'per-ent\

Definition of TRANSPARENT



1 a (1) : having the property of **transmitting** light without appreciable scattering so that bodies lying beyond are seen clearly : **PELLUCID** (2) : allowing the passage of a specified form of radiation (as X-rays or ultraviolet light)

b : fine or sheer enough to be seen through : **DIAPHANOUS**

2 a : free from pretense or deceit : **FRANK**

b : easily detected or seen through : **OBVIOUS**

c : readily understood

d : characterized by visibility or accessibility of information especially concerning business practices

— **trans·par·ent·ly** *adverb*

— **trans·par·ent·ness** *noun*



Business

- Underutilized expensive data
- Collaboration opportunities
- Fewer, smaller trials (10%)
- Be more transparent

Science

- New discoveries
- Better study planning
- Well informed, timely decisions

Personal

- Honoring patient contributions
- Better results, lower cost/ no waste
- It's us, our friends and family

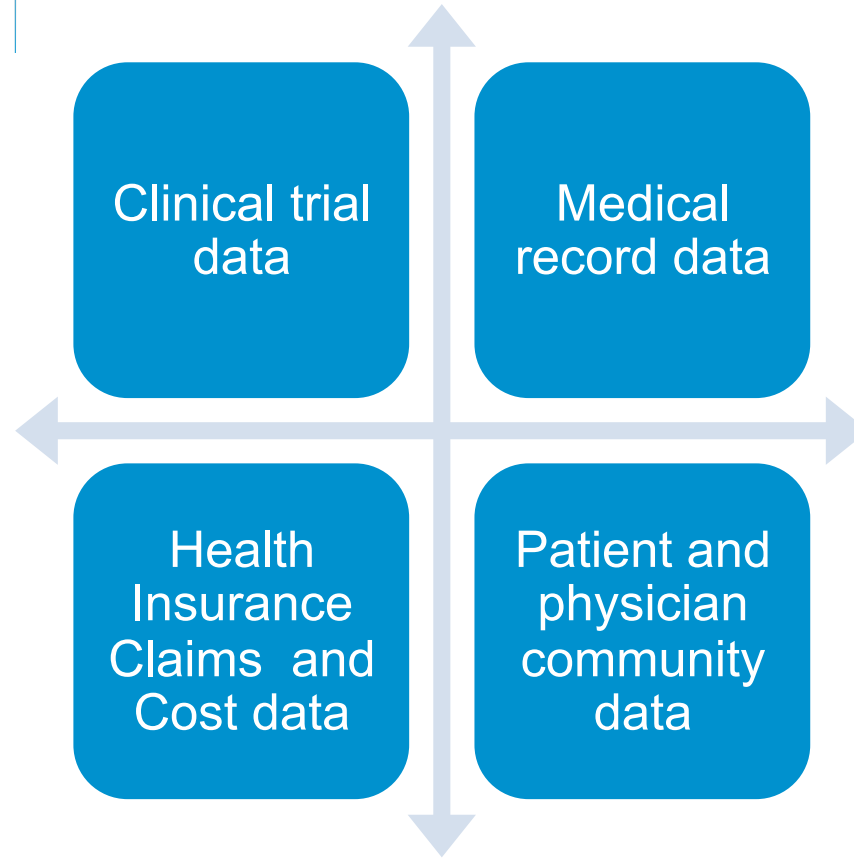
WHY NOW?



CONVERGING FORCES

- Regulatory/Health Authorities
 - EMA publish clinical-trial data and enable access to full data <https://www.clinicaltrialsregister.eu/> (ABPI monitoring) revising EU directive to include data
 - FDA <http://www.clinicaltrials.gov/> JANUS
 - NCI funded research publish data with the publication
- Patients
 - Patient advocacy groups
 - Informed and active patients
- Consortiums, other
 - CEO Roundtable LSC Task Force
 - NICE and the [AllTrials](#) campaign to make all clinical trial data available for public scrutiny

WHAT TYPE OF DATA ARE SUBJECT FOR INTERNAL AND EXTERNAL SCRUTINY ?



CONTRIBUTION OF CLINICAL DEVELOPMENT TO TRANSPARENCY

1. Enhance and analyze clinical data quality, continued dedication to audit & compliance
2. Standardize data, ready for analysis
3. Analyze data in early stage, before submission and after pooling of trial data

1. DATA QUALITY

DATA QUALITY TECHNIQUES IN CLINICAL DEVELOPMENT

- Master Data Management for clinical development

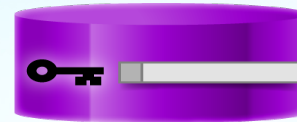
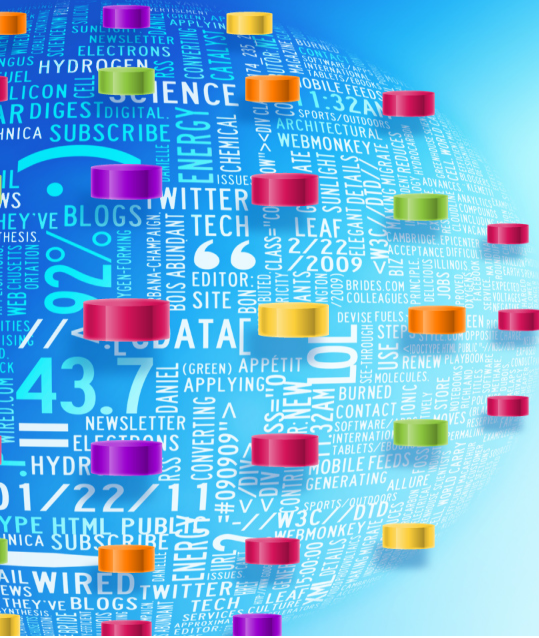
MDM FOR CLINICAL DEVELOPMENT

CONNECTING OPERATIONAL DATA SYSTEMS

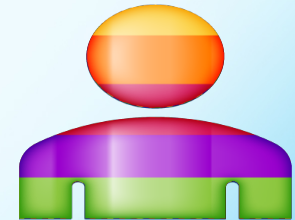


MDM FOR CLINICAL DEVELOPMENT

MANUAL CONNECTION OF PARTICIPANTS TAKES TIME



Clinical Programmer



Participant

WHAT IF WE HAVE A MASTER DECODER KEY RING?



Participant

MDM FOR CLINICAL DEVELOPMENT

MDM IS DIFFERENT THAN DATA WAREHOUSING

	Data Warehouse	MDM
Data Content	Historical content. Multiple, disparate subject areas. Integrated data.	Single subject area. Manages and maintains links to the authoritative source.
Usage	Analytics. Reporting and provisioning of historical, multi-subject area content. User-oriented; access via SQL.	Up-to-the-moment identification. Retrieve and synchronize data from other systems. System facing; SOA access.
Integration & Load	Batch loads typical. Transactional if latency is an issue.	Integrate data upon creation. Can be batch or real-time (online).
Data Transformation	Standardization unique to each DW. Code developed/maintained for each feed.	Master data elements standardized. Data manipulation is handled by centralized rules engine. Dramatically less maintenance.
Data Remediation	Data quality checking and cleansing recommended. Infrequently occurs.	Data cleansing and validation are core. Data can be cleansed in a manner transparent to the source system.

CDISC STANDARDS / SDTM WAREHOUSES

- Bringing data together across
- SAS Clinical Standards Toolkit and SAS Clinical Data Integration
- Enhanced data standardization leads to bringing together relevant domains more efficiently

QUESTIONS ENABLED BY AN SDTM WAREHOUSE

Which studies used efficacy parameter xx ?

How many subjects aged xx-xx had event xx in studies of a planned duration up to xx weeks and containing at least xx treated subjects ?

Were there any trends in the efficacy variable xx over time when comparing treatment groups xx and xx, and was this different for men and women ?

How many subjects were involved in phase I studies ?

Which studies had a crossover design (based on information in title/objectives)

CHALLENGE

FUNDAMENTAL PARADOX OF CLINICAL DATA WAREHOUSING RESOLVED

**Scientific
flexibility**



**Well-defined
standards**

Optimized to
address scientific
and medical
objectives

Easy adaptation
to new
requirements

Optimized for
integration and
standard analysis

Easy integration
and automation

CLINICAL WAREHOUSES

REQUIREMENTS

- Provides access to organizational data
 - Different source systems in clinical : Safety, EDC, CTMS, SAP
- Data is consistent
 - Coded against MedDRA version, lab normal ranges, AECODE
- Data can be separated and merged as needed
 - User should be able to merge and use analysis-ready data as required
- Data warehouse is not just data
 - Final transformation is not end-point of data
- Separate finalized from data “in a state of flux”
 - Closed studies and ongoing studies
- Data quality is of highest importance in a warehouse
 - Don't bring data together of mixed quality



SAS CLINICAL DATA INTEGRATION FEEDS SDTM WAREHOUSE (1)

- Data Harmonization
- Data Conversion and Mapping
- Missing Data
- Possibly, Processing / Calculation (derived data)

SAS CLINICAL DATA INTEGRATION

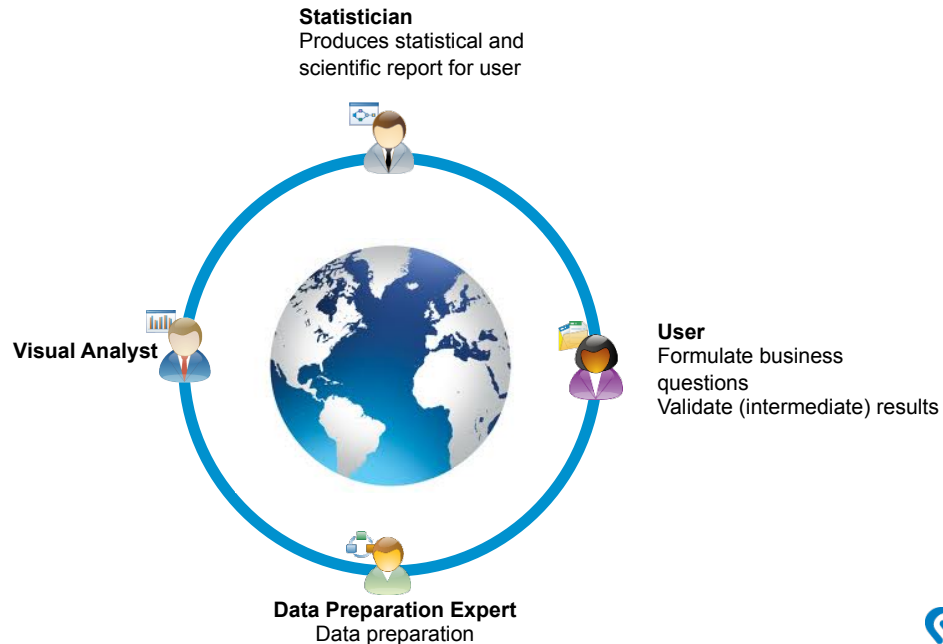


SAS CLINICAL DATA INTEGRATION FEEDS SDTM WAREHOUSE (2)

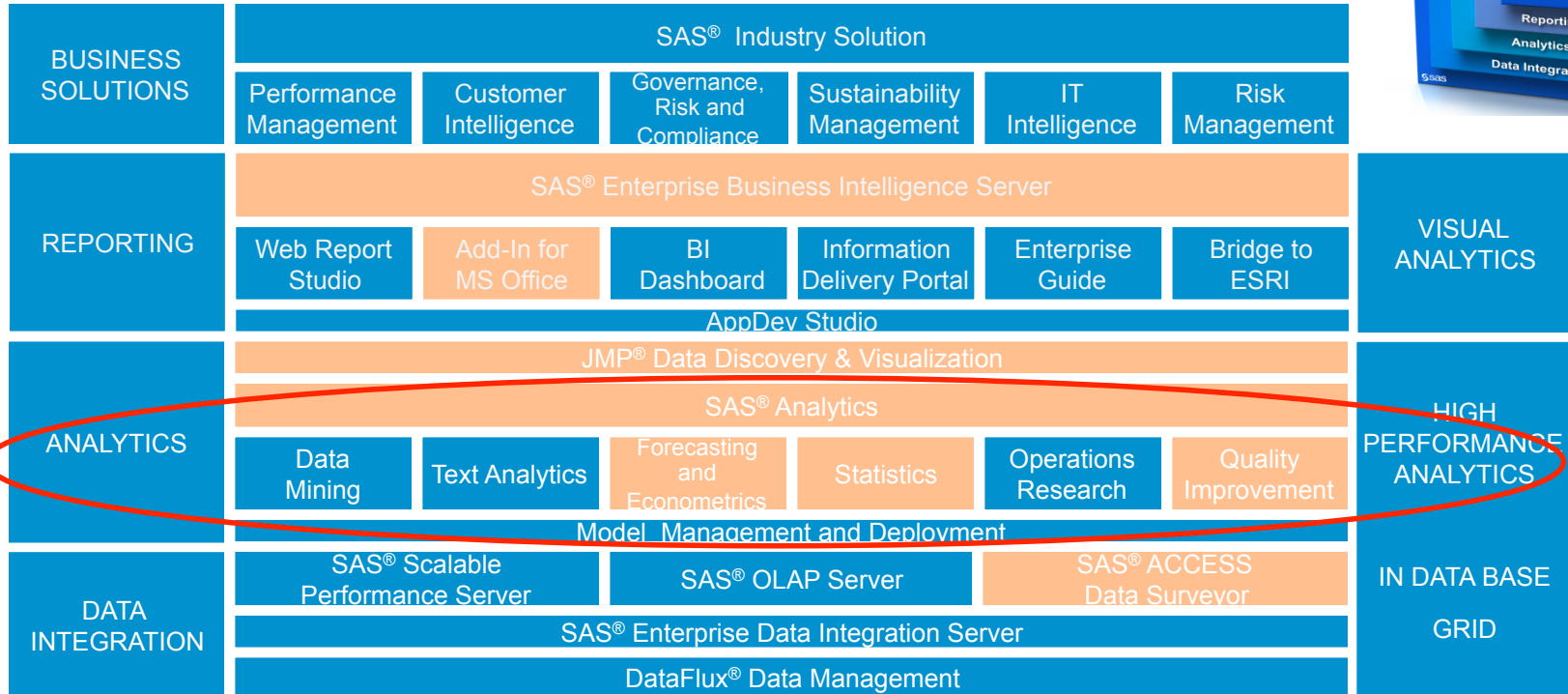
- Near real-time or high-frequent EDC extraction based on ODM
- Built-in SDTM (CDISC), ADaM, SEND, CRT-DDS, ... data models
- Check data consistency against SDTM
- Re-use for standard SDTM domains (warehouse)
- Data integration technology integrated :
 - Data Integration library for managing incremental data transfers
 - XML transfer capabilities
 - Reading from source system and writing to SAS Drug Development
- Next version of SAS CDI will be able to read `define.xml` and translate in standards templates

3. ANALYTICS

- Real-time and visual analysis of clinical data
- Analysis of efficacy and safety
- Cost-effectiveness or the fourth hurdle



SAS® BUSINESS ANALYTICS FRAMEWORK



PRODUCT PORTFOLIO OVERVIEW

SAS® BUSINESS ANALYTICS FRAMEWORK



BUSINESS SOLUTIONS	SAS® Industry Solution					
	Performance Management	Customer Intelligence	Governance, Risk and Compliance	Sustainability Management	IT Intelligence	Risk Management
REPORTING	SAS® Enterprise Business Intelligence Server					
	Web Report Studio	Add-In for MS Office	BI Dashboard	Information Delivery Portal	Enterprise Guide	Bridge to ESRI
	AppDev Studio					
ANALYTICS	JMP® Data Discovery & Visualization					
	SAS® Analytics					
	Data Mining	Text Analytics	Forecasting and Econometrics	Statistics	Operations Research	Quality Improvement
	Model Management and Deployment					
	SAS® Scalable Performance Server					
DATA INTEGRATION	SAS® OLAP Server		SAS® ACCESS Data Surveyor			
	SAS® Enterprise Data Integration Server					
	DataFlux® Data Management					

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VISUAL ANALYTICS

HIGH PERFORMANCE ANALYTICS

IN DATA BASE GRID

Anmelden bei SAS®

[Info](#)



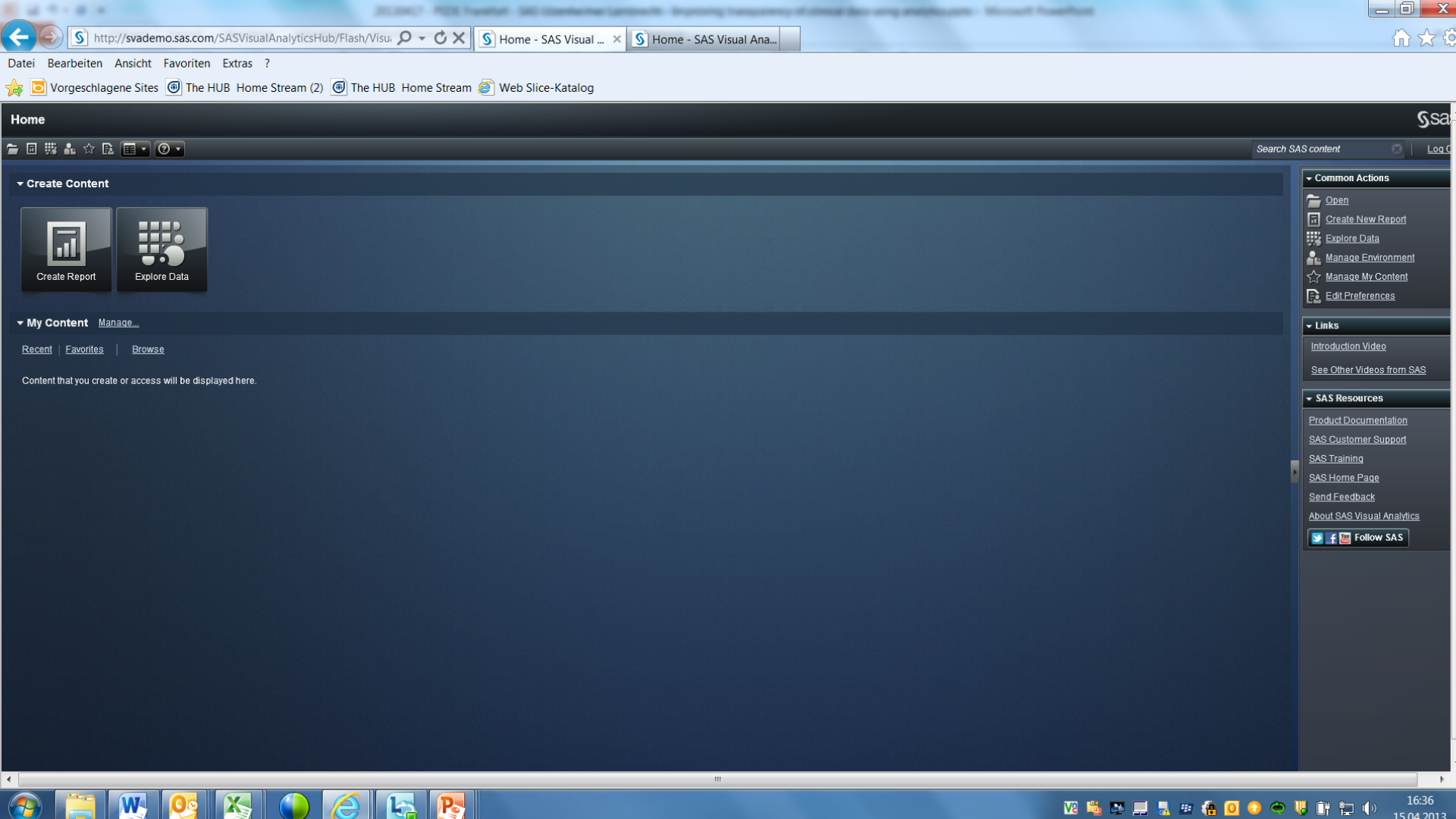
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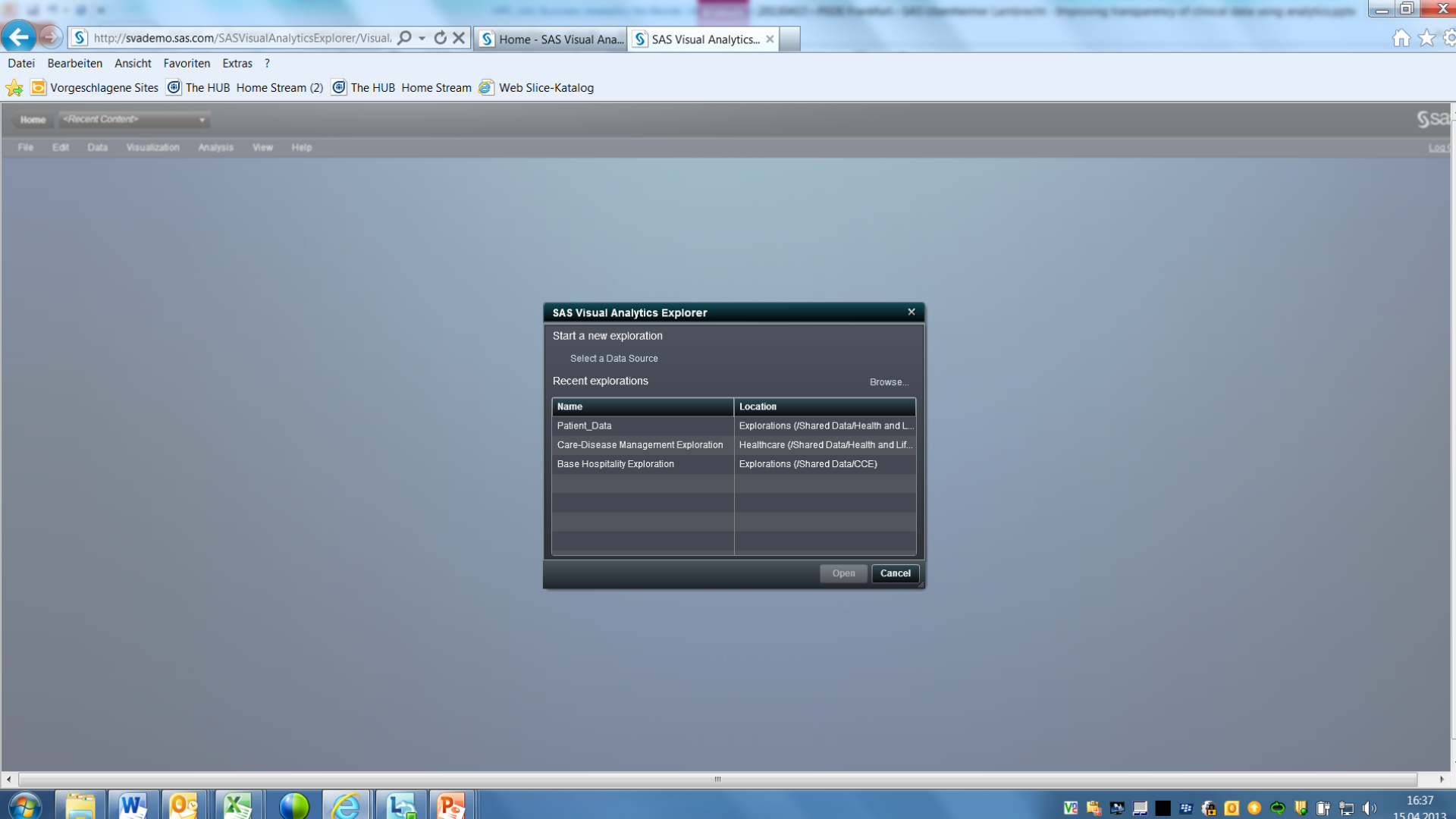
gerheu

Kennwort:

••••••••

Anmelden





SAS Visual Analytics Explorer

Start a new exploration

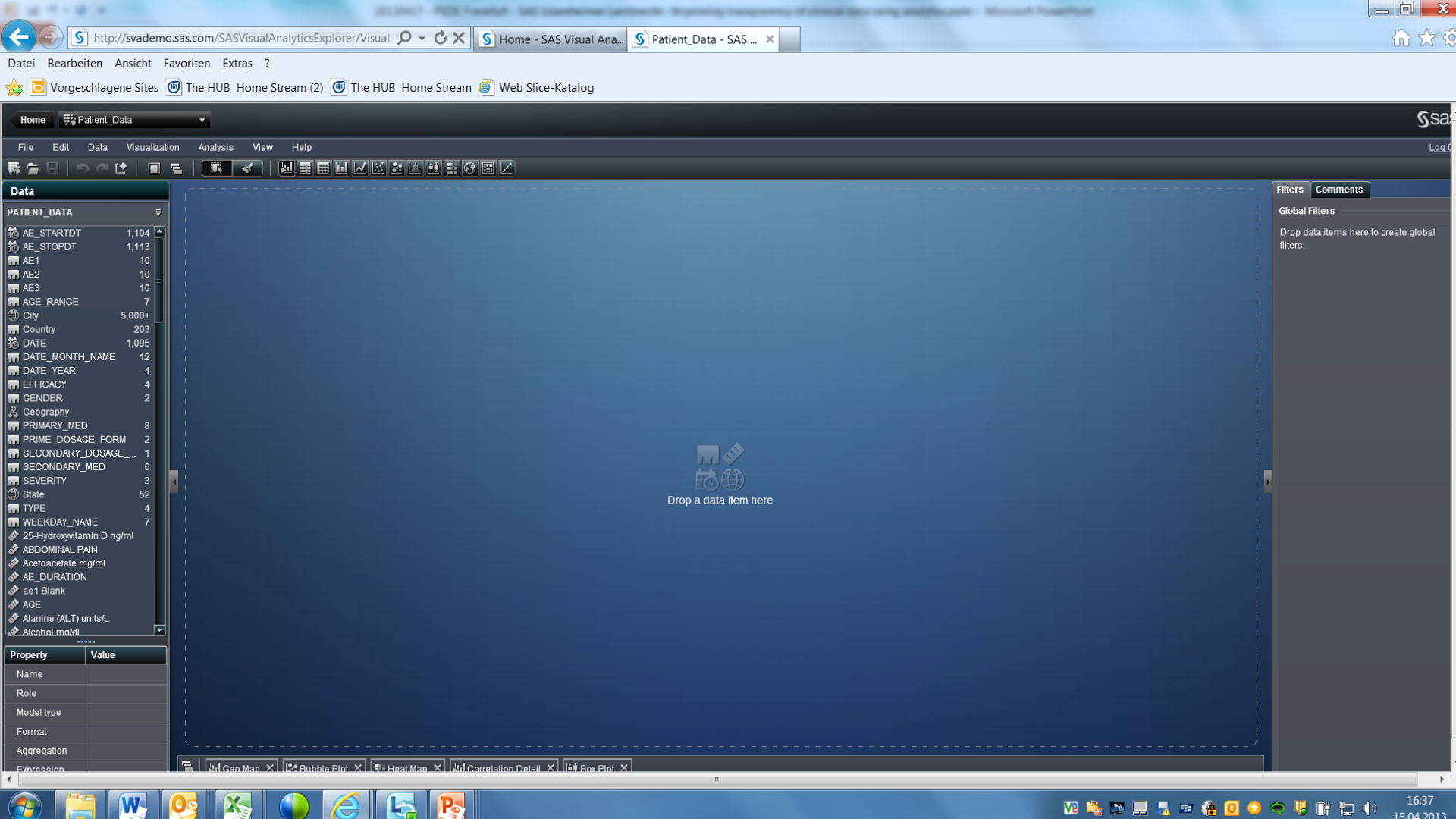
Select a Data Source

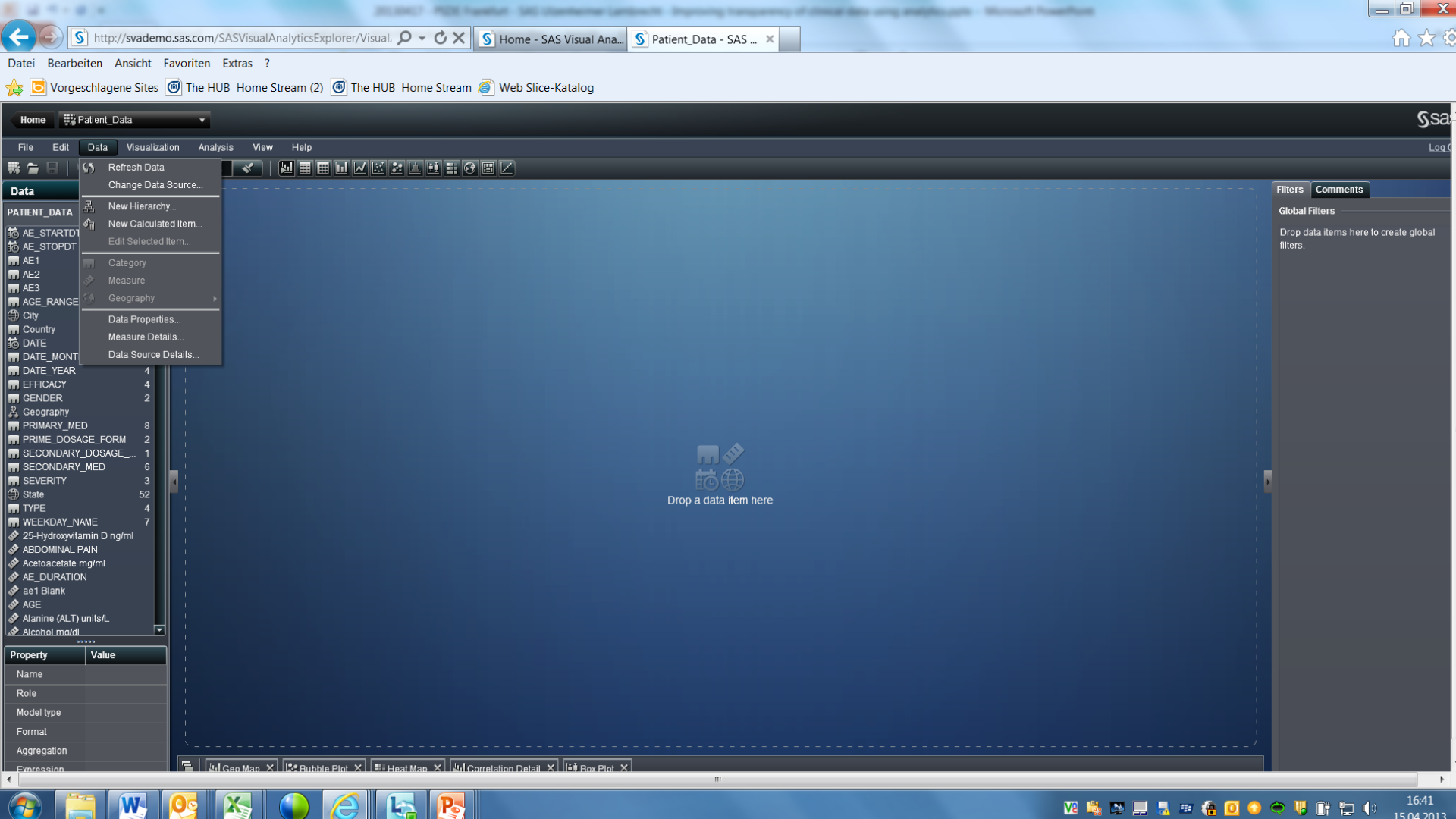
Recent explorations

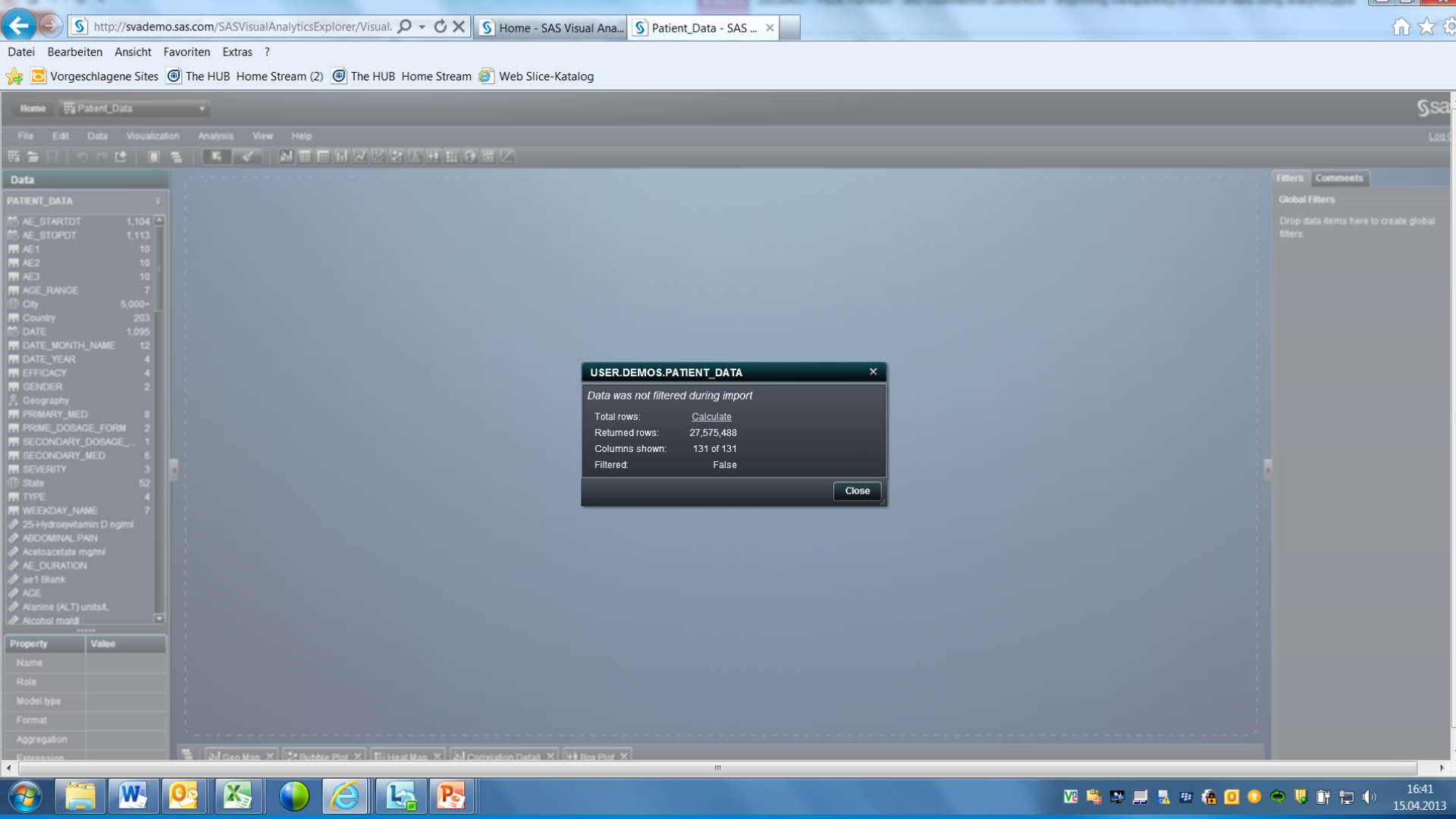
Browse...

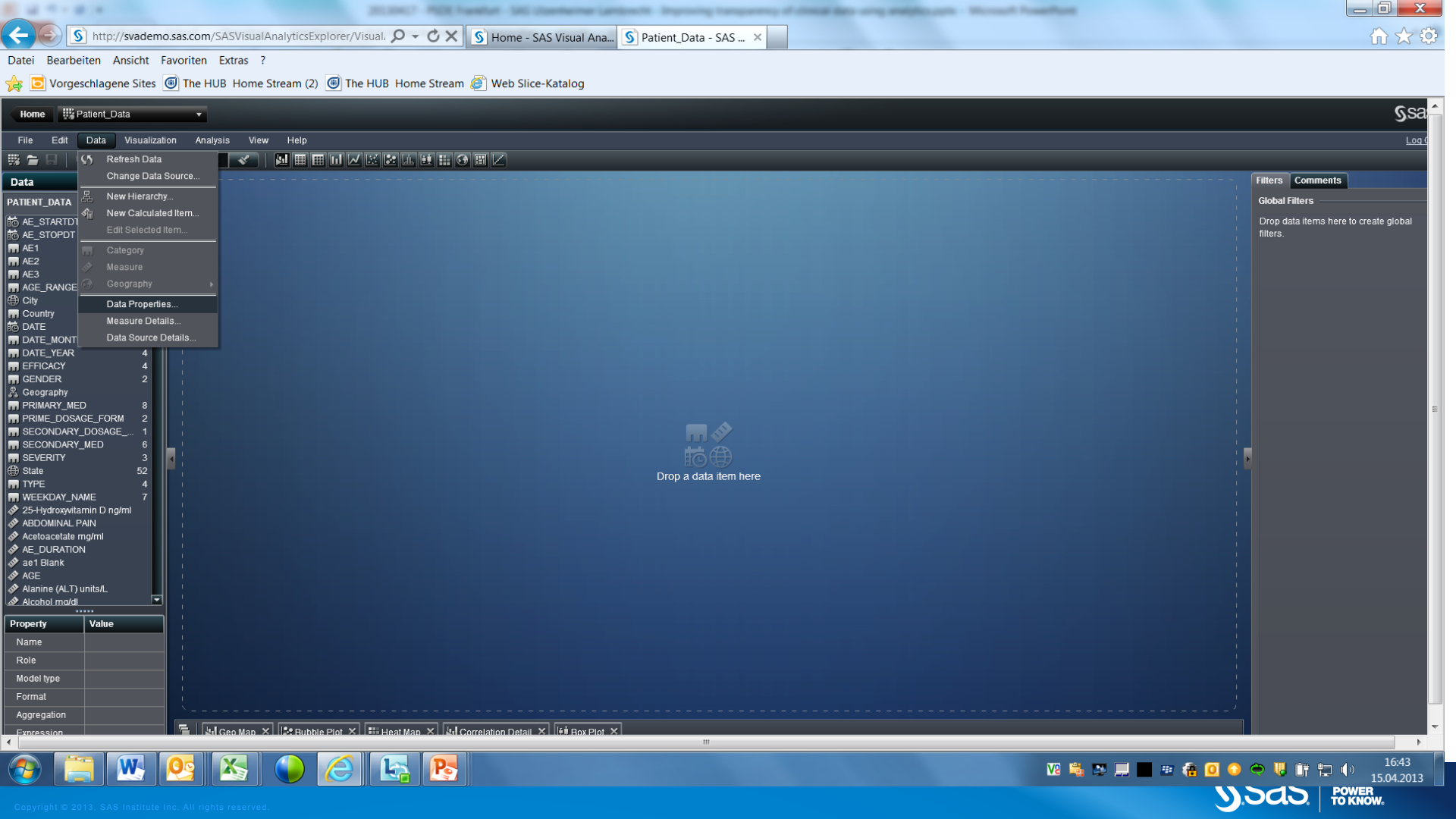
Name	Location
Patient_Data	Explorations (/Shared Data/Health and L...
Care-Disease Management Exploration	Healthcare (/Shared Data/Health and Lif...
Base Hospitality Exploration	Explorations (/Shared Data/CCE)

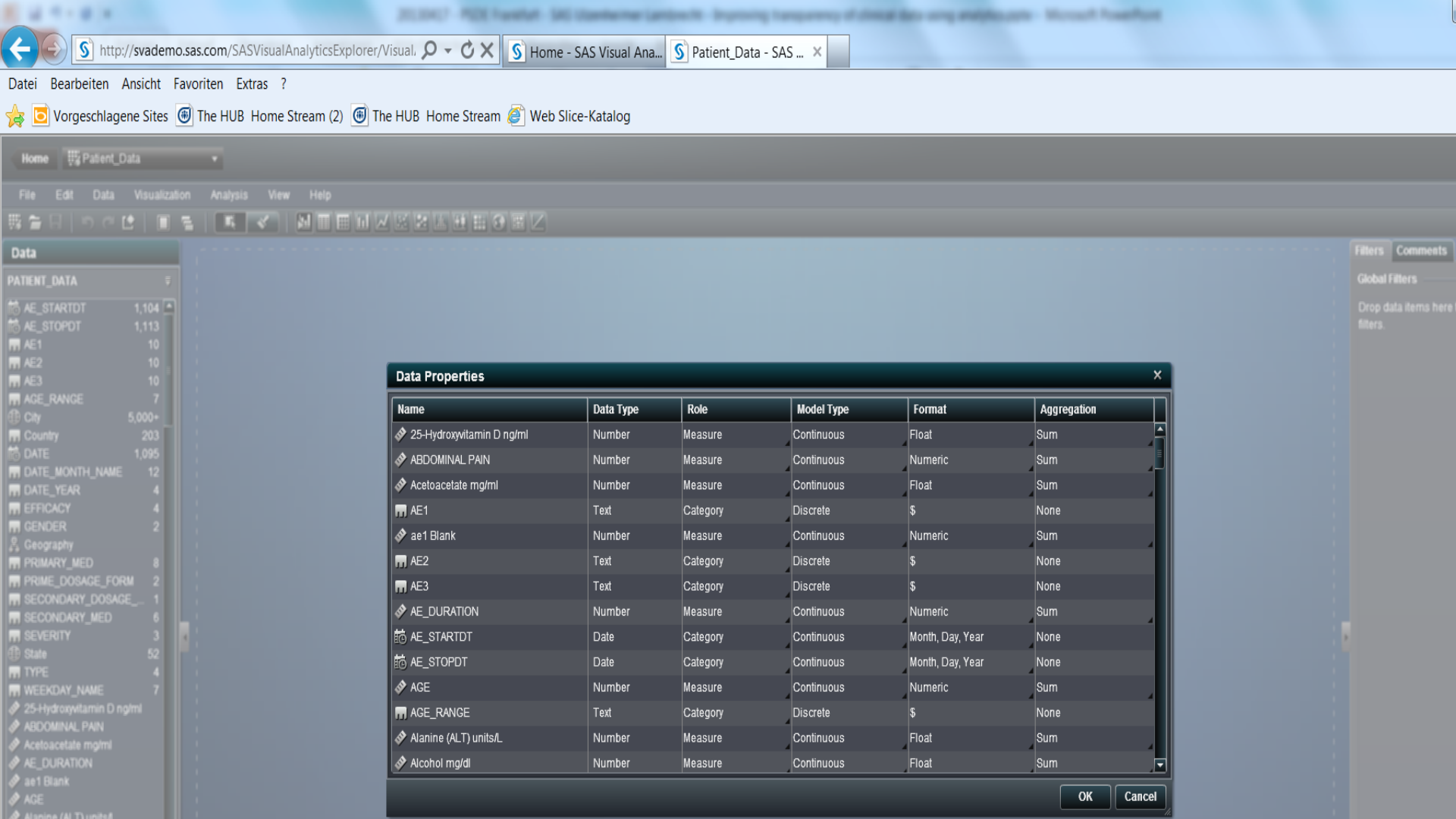
OpenCancel









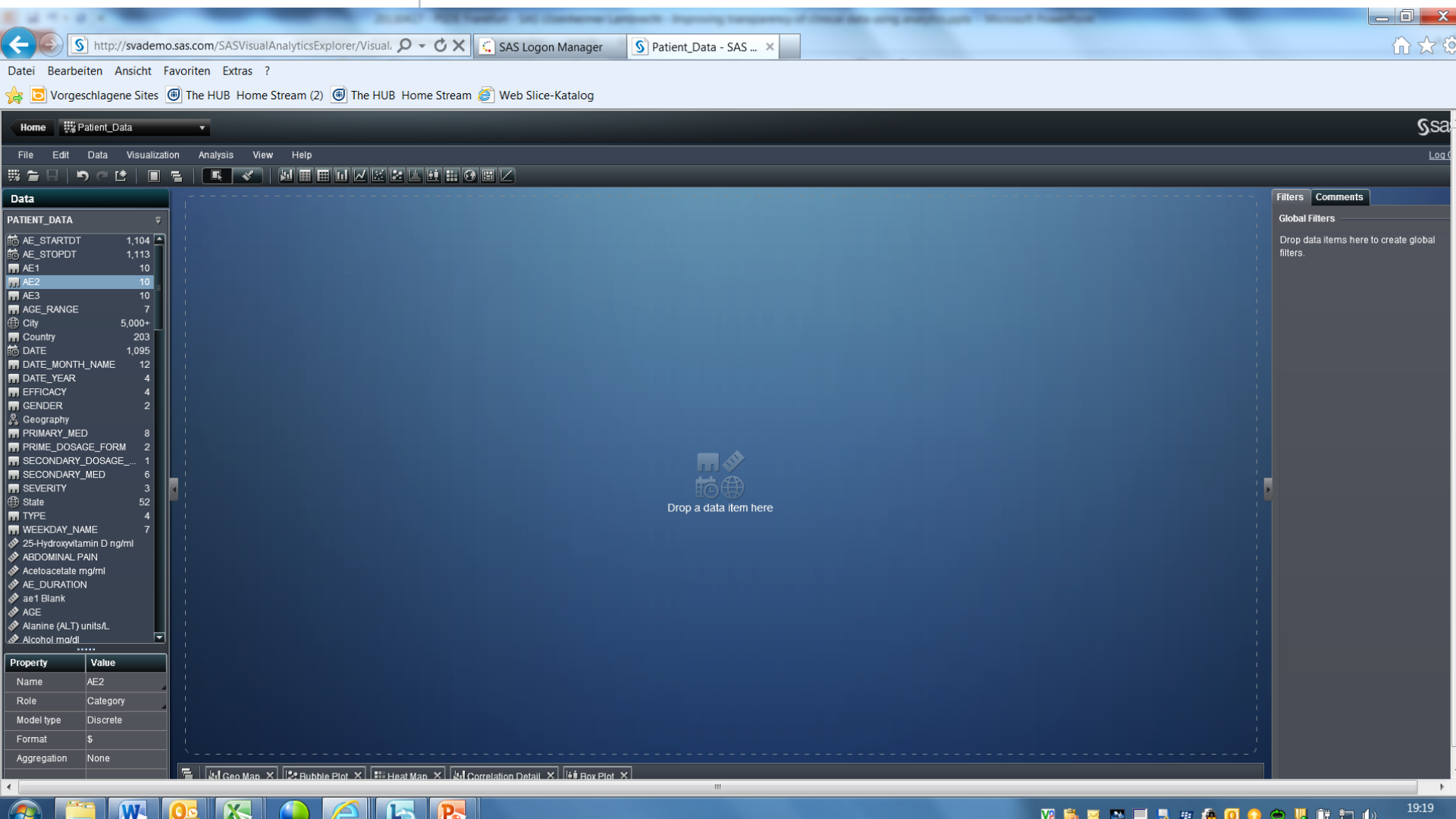


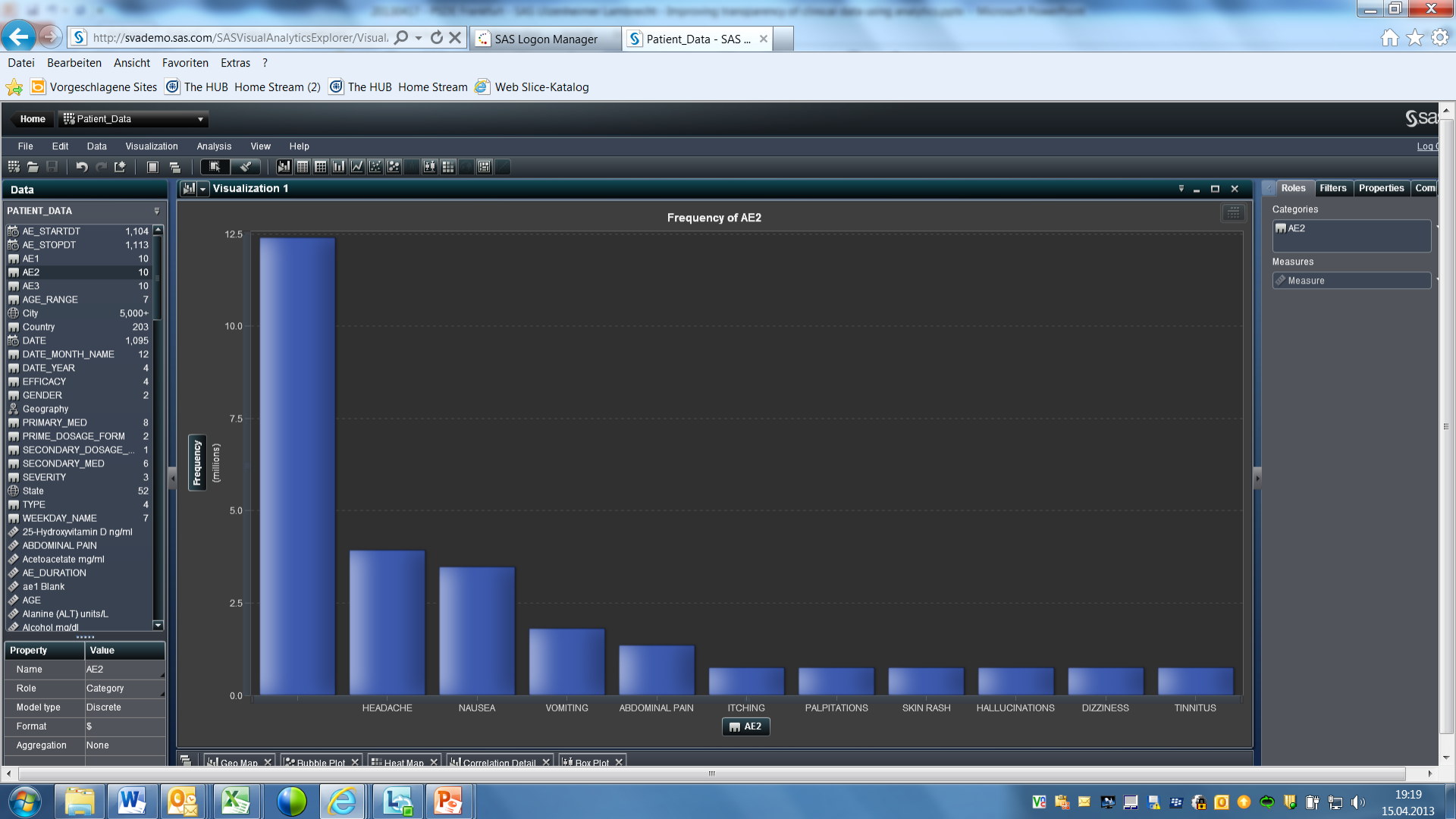
Data Properties

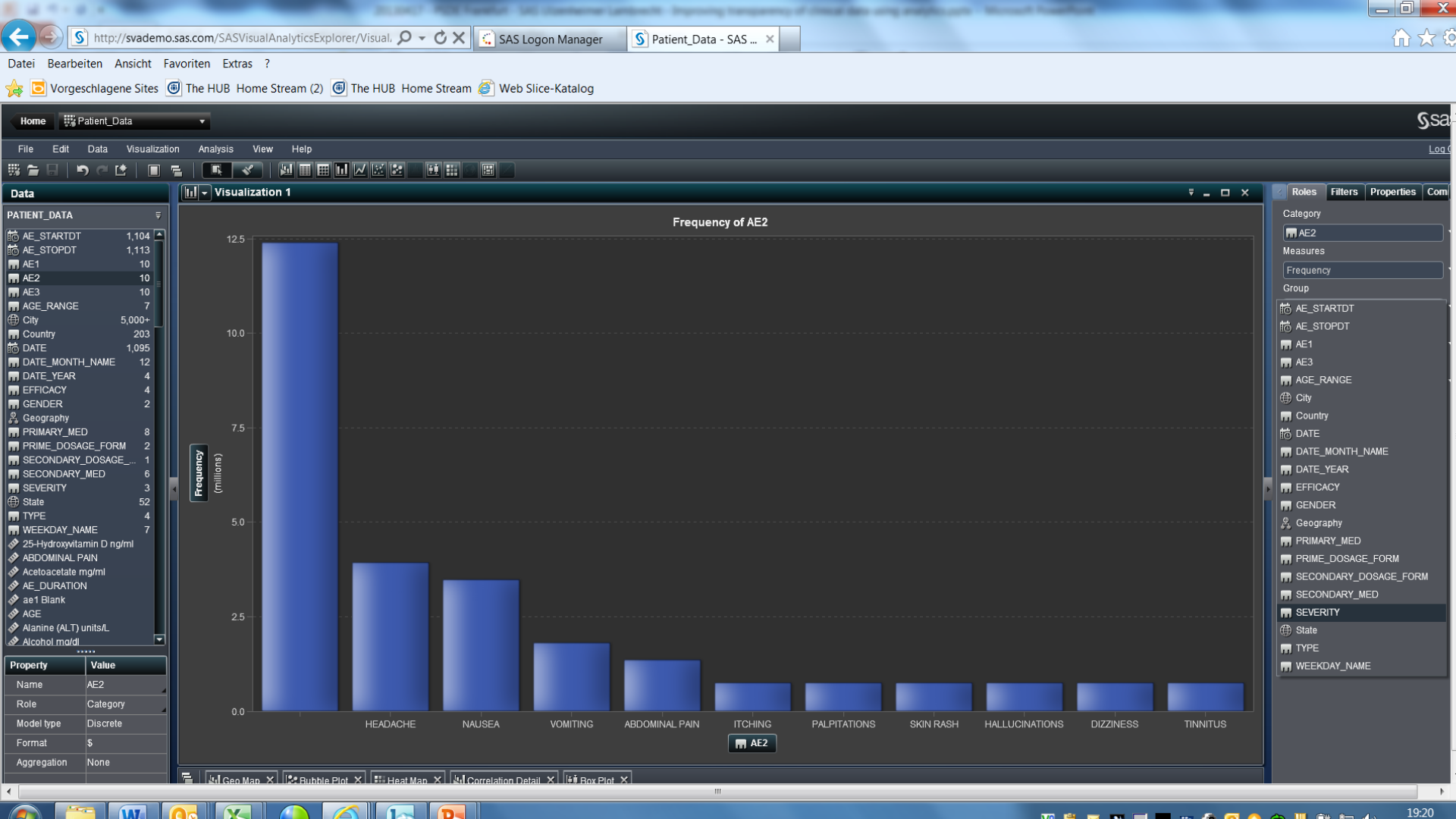
Name	Data Type	Role	Model Type	Format	Aggregation
25-Hydroxyvitamin D ng/ml	Number	Measure	Continuous	Float	Sum
ABDOMINAL PAIN	Number	Measure	Continuous	Numeric	Sum
Acetoacetate mg/ml	Number	Measure	Continuous	Float	Sum
AE1	Text	Category	Discrete	\$	None
ae1 Blank	Number	Measure	Continuous	Numeric	Sum
AE2	Text	Category	Discrete	\$	None
AE3	Text	Category	Discrete	\$	None
AE_DURATION	Number	Measure	Continuous	Numeric	Sum
AE_STARTDT	Date	Category	Continuous	Month, Day, Year	None
AE_STOPDT	Date	Category	Continuous	Month, Day, Year	None
AGE	Number	Measure	Continuous	Numeric	Sum
AGE_RANGE	Text	Category	Discrete	\$	None
Alanine (ALT) units/L	Number	Measure	Continuous	Float	Sum
Alcohol mg/dl	Number	Measure	Continuous	Float	Sum

OK

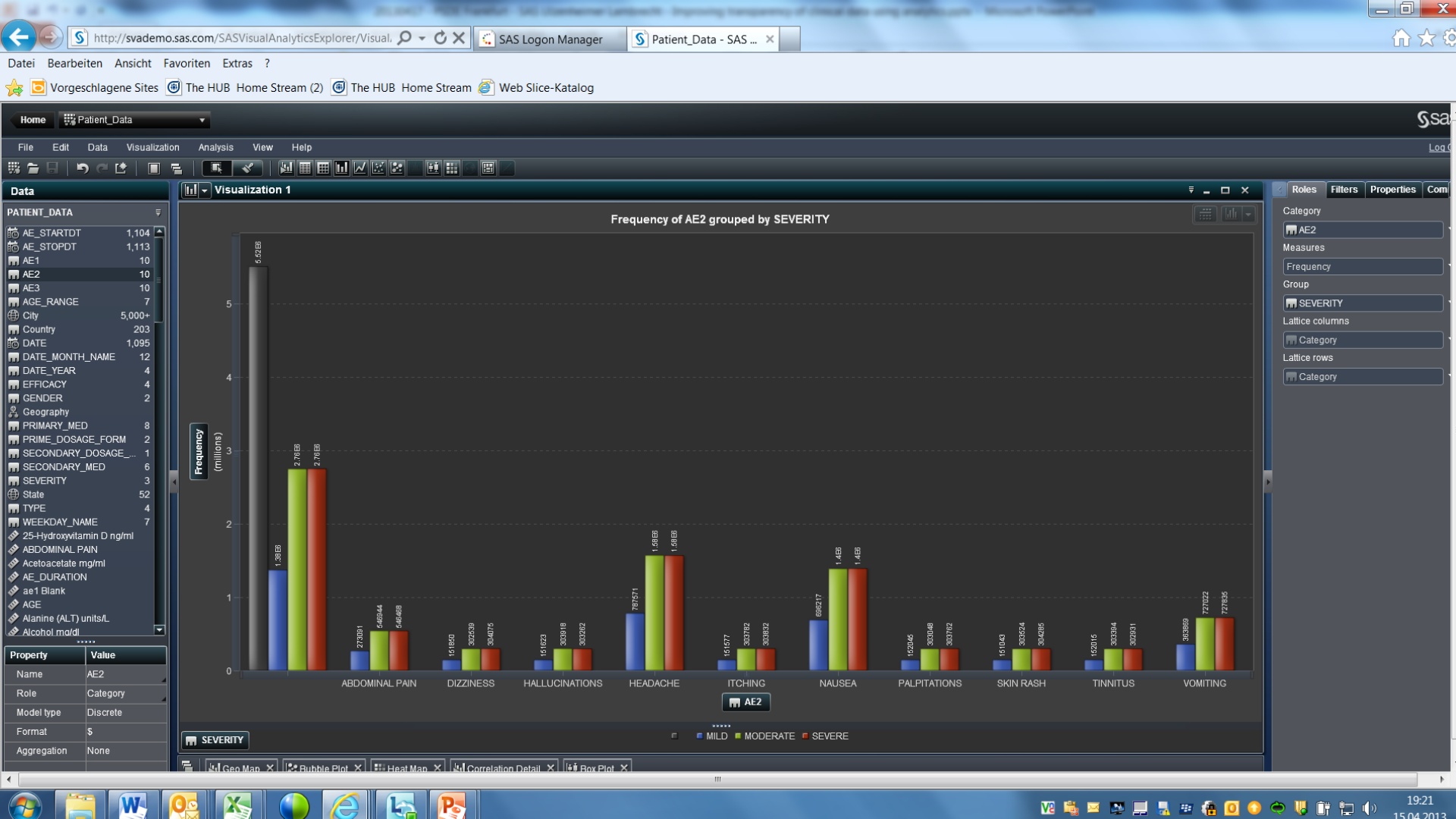
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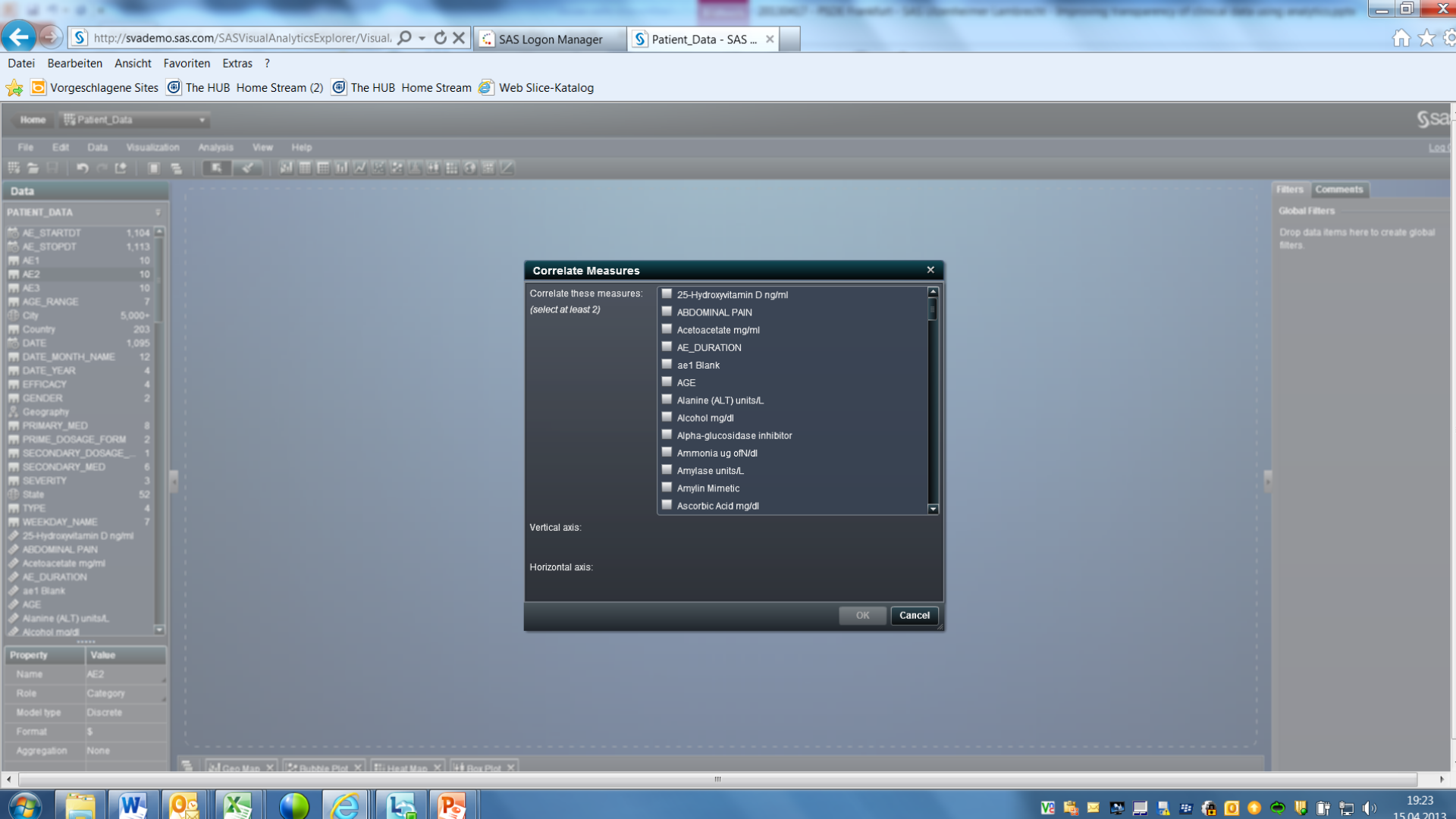


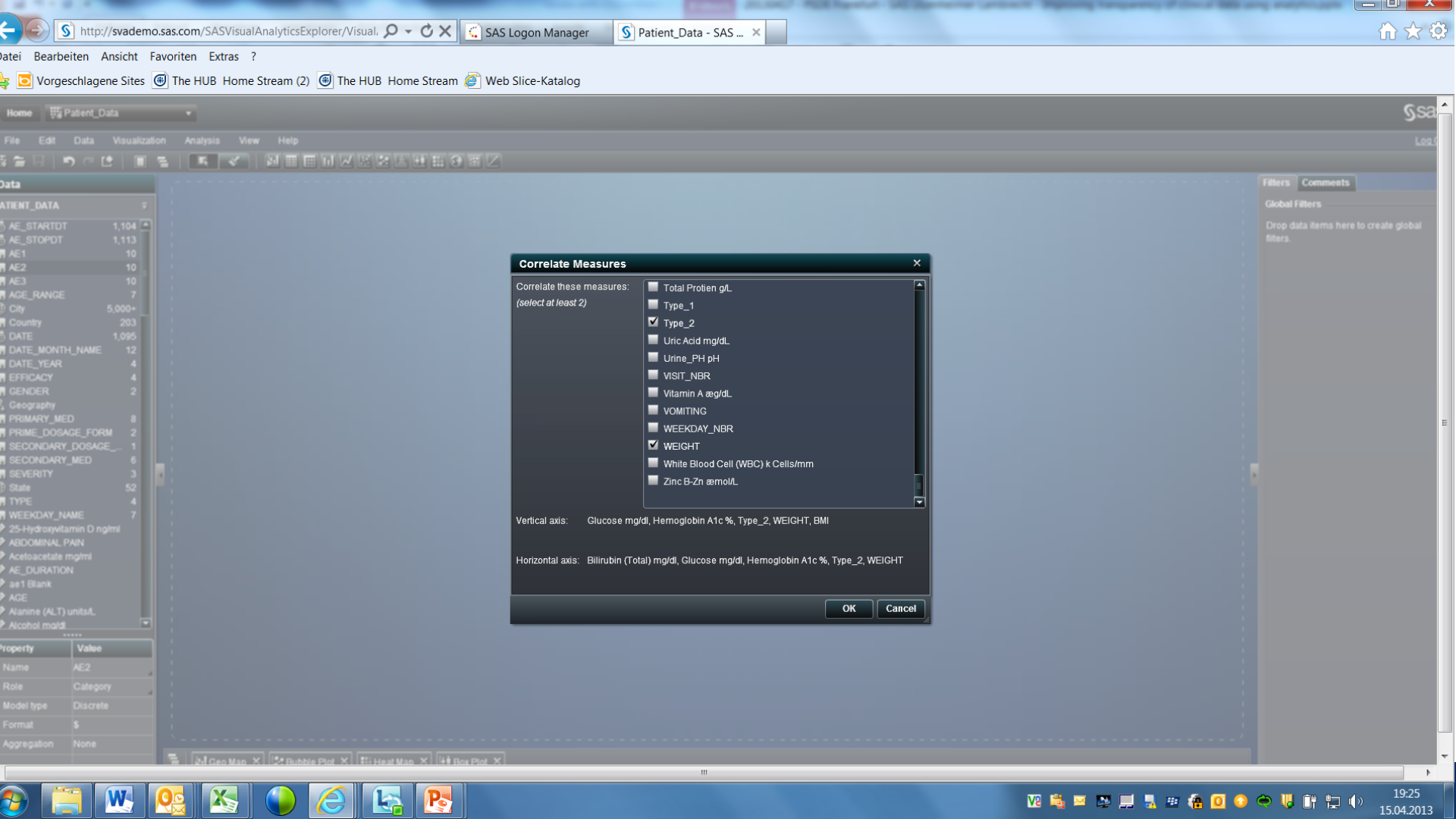














Data

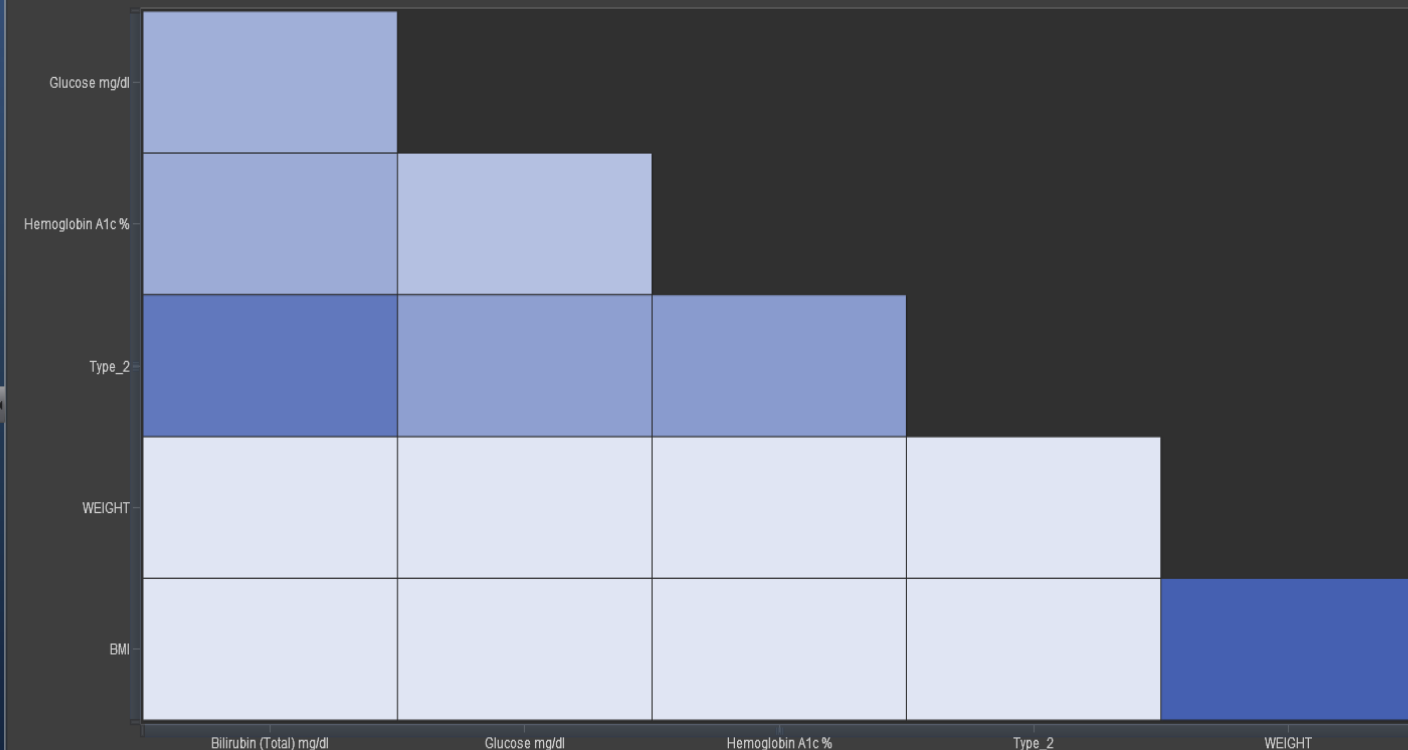
PATIENT_DATA

AE_STARTDT	1,104
AE_STOPDT	1,113
AE1	10
AE2	10
AE3	10
AGE_RANGE	7
City	5,000+
Country	203
DATE	1,095
DATE_MONTH_NAME	12
DATE_YEAR	4
EFFICACY	4
GENDER	2
Geography	
PRIMARY_MED	8
PRIME_DOSAGE_FORM	2
SECONDARY_DOSAGE...	1
SECONDARY_MED	6
SEVERITY	3
State	52
TYPE	4
WEEKDAY_NAME	7
25-Hydroxyvitamin D ng/ml	
ABDOMINAL PAIN	
Acetoacetate mg/ml	
AE_DURATION	
ae1 Blank	
AGE	
Alanine (ALT) units/L	
Alcohol mg/dl	

Property	Value
Name	AE2
Role	Category
Model type	Discrete
Format	\$
Aggregation	None

Visualization 1

Correlation of selected measures



Weak

Strong

Roles Filters Properties Com

Measures

- Bilirubin (Total) mg/dl
- Glucose mg/dl
- Hemoglobin A1c %
- Type_2
- WEIGHT
- BMI

