

Single Day Event

Automate Clinical Study Report

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Disclaimer

The information included in this presentation represents the opinion of the speaker, no way related to Bayer pharmaceutical.



Automate Clinical Study Report

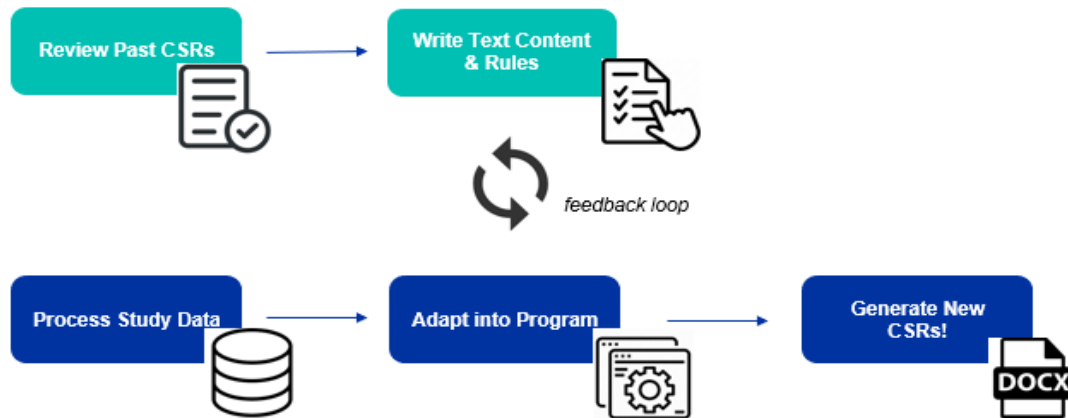
- Clinical Study Report (CSR) writing is a complex process that involves various stakeholders and data sources.
- Automation in CSR writing provides quality and consistency across different submission dossiers which includes CSR's, and summaries of safety and efficacy.
- Medical writers can work within an interactive environment and easily produce their draft CSR reducing their repetitive tasks and enabling them to focus on key aspects of interpretation of results and generating insights.



Data and Rules Preparation

- // Statisticians and Medical Writers jointly determine the tables, listings and figures (TLFs)
- // TLFs are programmed, validated and executed by the Statistical Analyst using SAS
- // At the time of execution, metadata is produced for each executed TLF

Rule development:





Data Transformation

// In each module, the business logic (i.e. “rules”) that process the metadata is present. It produces the text for that dashboard.

// Computation is not very complex, and amounts to filtering, reg-ex queries, parsing and producing the final narrative text.

// This is dependent on the incoming metadata and original table following a standard layout from a prescribed TLF catalog.

	col4 Total@N=25 (100%)	col1 Placebo@N= (100%)	col2 Xanomeline High Dose@N=84 (100%)	col3 Xanomeline Low Dose@N=84 (100%)	text	_nr_	_kind_ order variable	_ord_ order variable	_newnar order variable
1.					Age	1	.	.	.
2	254	86	84	84	n	1	.	.	.
3	75.1 (8.2)	75.2 (8.6)	74.4 (7.9)	75.7 (8.3)	Mean (SD)	1	.	.	.
4	77.0	76.0	76.0	77.5	Median	1	.	.	.
5	51, 89	52, 89	56, 88	51, 88	Min, Max	1	.	.	.
6					Age Category 1	1	0	1	1
7	144 (56.7...)	42 (48.8%)	55 (65.5%)	47 (56.0%)	65-80	1	9	1	2
8	33 (13.0...)	14 (16.3%)	11 (13.1%)	8 (9.5%)	<65	1	9	2	2
9	77 (30.3...)	30 (34.9%)	18 (21.4%)	29 (34.5%)	>80	1	9	3	2
10					Race	2	0	1	1
11	1 (0.4%)	0	1 (1.2%)	0	AMERICAN INDIAN OR ALASKA NATIVE	2	9	1	2
12	23 (9.1%)	8 (9.3%)	9 (10.7%)	6 (7.1%)	BLACK OR AFRICAN AMERICAN	2	9	2	2
13	230 (90.6...)	78 (90.7%)	74 (88.1%)	78 (92.9%)	WHITE	2	9	3	2
14					Sex	3	0	1	1
15	143 (56.3...)	53 (61.6%)	40 (47.6%)	50 (59.5%)	F	3	9	1	2
16	111 (43.7...)	33 (38.4%)	44 (52.4%)	34 (40.5%)	M	3	9	2	2
17					Ethnicity	4	0	1	1
18	12 (4.7%)	3 (3.5%)	3 (3.6%)	6 (7.1%)	HISPANIC OR LATINO	4	9	1	2
19	242 (95.3...)	83 (96.5%)	81 (96.4%)	78 (92.9%)	NOT HISPANIC OR LATINO	4	9	2	2
20					Baseline BMI (kg/m^2)	2	.	.	.
21	253	86	84	83	n	2	.	.	.
22	24.67 (4....)	23.64 (3....)	25.35 (4....)	25.06 (4....)	Mean (SD)	2	.	.	.
23	24.20	23.40	24.80	24.30	Median	2	.	.	.
24	13.7, 40.1	15.1, 33.3	13.7, 34.5	17.7, 40.1	Min, Max	2	.	.	.
25					Baseline Height (cm)	3	.	.	.
26	254	86	84	84	n	3	.	.	.
27	163.93 (1....)	162.57 (1....)	165.82 (1....)	163.43 (1....)	Mean (SD)	3	.	.	.
28	162.85	162.60	165.10	162.60	Median	3	.	.	.
29	135.9, 195.6	137.2, 185.4	146.1, 190.5	135.9, 195.6	Min, Max	3	.	.	.
30					Baseline Weight (kg)	4	.	.	.
31	253	86	84	83	n	4	.	.	.
32	66.65 (14....)	62.76 (12....)	70.00 (14....)	67.28 (14....)	Mean (SD)	4	.	.	.
33	66.70	60.55	69.20	64.90	Median	4	.	.	.
34	34.0, 108.0	34.0, 86.2	41.7, 108.0	45.4, 106.1	Min, Max	4	.	.	.
35					Safety Population Flag	5	0	1	1
36	254 (100....)	86 (100.0%)	84 (100.0%)	84 (100.0%)	Y	5	9	1	2



User Experience

Disposition

Screening

Treatment

Protocol Deviations

Analysis Sets

More Tables

Demographics

Demographics

Baseline Characteristics

More Tables

Patient History

Medical History Findings

Prior Meds

Concomitant Meds

Anti-Cancer Therapy

More Tables

Exposure

Exposure - 1st Drug

Exposure - 2nd Drug

Dose Mods - 1st Drug

Dose Mods - 2nd Drug

More Tables

Medical History Findings

Search:

Choose a Table

Table: Medical history: number of subjects with findings by primary system organ class and preferred term

Table: Medical history: number of subjects with findings by primary system organ class and preferred term

Showing 1 to 2 of 2 entries

Generate Content

Table

Table: Medical history: number of subjects with findings by primary system organ class and preferred term

Primary system organ class Preferred term MedDRA version 23.1	Placebo N=64 (100%)	Xanomeline High Dose N=64 (100%)	Xanomeline Low Dose N=64 (100%)	Total N=254 (100%)
Number (%) of subjects with at least one medical history finding	69 (80.2%)	79 (84.0%)	77 (81.7%)	225 (88.6%)
CARDIAC DISORDERS	13 (15.1%)	18 (21.4%)	13 (15.5%)	44 (17.3%)
GASTROINTESTINAL DISORDERS	17 (18.8%)	21 (23.9%)	15 (17.9%)	55 (20.9%)
DIARRHOEA	9 (10.5%)	4 (4.8%)	5 (6.0%)	18 (7.3%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	21 (24.4%)	40 (47.6%)	47 (56.0%)	108 (42.5%)
APPLICATION SITE DERMATITIS	5 (5.8%)	7 (8.3%)	9 (10.7%)	21 (8.3%)
APPLICATION SITE ERYTHEMA	3 (3.5%)	15 (17.9%)	12 (14.3%)	30 (11.8%)
APPLICATION SITE IRRITATION	3 (3.5%)	9 (10.7%)	9 (10.7%)	21 (8.3%)
APPLICATION SITE PRURITUS	6 (7.0%)	22 (26.2%)	22 (26.2%)	50 (19.7%)
INFECTIONS AND INFESTATIONS	16 (18.6%)	13 (15.5%)	10 (11.9%)	39 (15.4%)
INVESTIGATIONS	10 (11.6%)	6 (7.1%)	7 (8.3%)	23 (9.1%)
NERVOUS SYSTEM DISORDERS	12 (14.0%)	27 (32.1%)	20 (23.8%)	59 (23.2%)
DIZZINESS	2 (2.3%)	12 (14.3%)	8 (9.5%)	22 (8.7%)
PSYCHIC DISORDERS	10 (11.6%)	9 (10.7%)	10 (11.9%)	29 (11.4%)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	10 (11.6%)	10 (11.9%)	10 (11.9%)	30 (11.8%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	21 (24.4%)	42 (50.0%)	42 (50.0%)	105 (41.3%)
ERYTHEMA	9 (10.5%)	14 (16.7%)	15 (17.9%)	38 (15.0%)
PRURITUS	8 (9.3%)	26 (31.0%)	23 (27.4%)	57 (22.4%)
RASH	5 (5.8%)	11 (13.1%)	13 (15.5%)	29 (11.4%)

A subject is counted only once within each primary SOC / preferred term.

Arms

Choose Arm 1

Placebo

Choose Arm 2

Xanomeline High Dose

Only Report on Total?

Choose Total Arm

Placebo

Filtering

Minimum display threshold (%)

10

Arm 1 is at least X(%) higher threshold

0

Arm 1 is at least X(%) lower threshold

0

Display

Display levels:

System Organ Class (SOC)

Preferred Term (PT)

Reset

Introduction

Summary

Most Common SOC

The most common findings reported in the SOC were general disorders and administration site conditions (24.4%), skin and subcutaneous tissue disorders (24.4%), and gastrointestinal disorders (19.8%) in Placebo, and skin and subcutaneous tissue disorders (50.0%), general disorders and administration site conditions (47.6%), and nervous system disorders (32.1%) in Xanomeline High

Most Common PT

Additional Text

Reference



Results

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A listing of all participants included in each analysis set, including reasons for their exclusion from the appropriate analysis set can be found in [Section 16.2.3](#).

8.4 Database errata

Database errata can be found in [Section 16.4.2](#).

8.5 Demographics and baseline characteristics

Demographics

Demographics for the study participants are described in Table X. Demographics were generally well-balanced between the treatment arms. (NOTE TO MW TO ADAPT/DELETE THIS SENTENCE AS NEEDED.)

In Placebo, 61.6% of the participants were female and 38.4% were male. In Xanomeline High Dose, 47.6% were female and 52.4% were male.

Most participants in Placebo were White (90.7%), followed by Black or African American (9.3%). Most participants in Xanomeline High Dose were White (88.1%), followed by Black or African American (10.7%) and American Indian or Alaska Native (1.2%).

The median age of participants was 76.0 years (range 52 - 89 years) in Placebo and 76.0 years (range 56 - 88 years) in Xanomeline High Dose.

A participant listing of demographics is provided in [Section 16.2.4](#).

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Table: Demographics (safety analysis set)

	Placebo N=88 (100%)	Xanomeline High Dose N=84 (100%)	Xanomeline Low Dose N=84 (100%)	Total N=254 (100%)
Age				
n	88	84	84	254
Mean (SD)	75.2 (8.6)	74.4 (7.9)	75.7 (8.3)	75.1 (8.2)
Median	76.0	76.0	77.0	77.0
Min, Max	51, 89	56, 88	51, 88	51, 89
Age Category 1				
65-80	42 (48.8%)	55 (65.5%)	47 (56.0%)	144 (56.7%)
<65	14 (16.3%)	11 (13.1%)	8 (9.5%)	33 (13.0%)
>80	30 (34.9%)	18 (21.4%)	29 (34.5%)	77 (30.3%)
Race				
AMERICAN INDIAN OR ALASKA NATIVE	0	1 (1.2%)	0	1 (0.4%)
BLACK OR AFRICAN AMERICAN	8 (9.3%)	9 (10.7%)	6 (7.1%)	23 (9.1%)
WHITE	78 (90.7%)	74 (88.1%)	78 (92.9%)	230 (90.6%)
Sex				
F	53 (61.6%)	40 (47.6%)	50 (59.5%)	143 (56.3%)
M	33 (38.4%)	44 (52.4%)	34 (40.5%)	111 (43.7%)
Ethnicity				
HISPANIC OR LATINO	3 (3.5%)	3 (3.6%)	6 (7.1%)	12 (4.7%)
NOT HISPANIC OR LATINO	83 (96.5%)	81 (96.4%)	78 (92.9%)	242 (95.3%)
Baseline BMI (kg/m ²)				
n	88	84	83	253
Mean (SD)	23.84 (3.87)	25.35 (4.16)	25.08 (4.27)	24.67 (4.09)
Median	23.40	24.60	24.50	24.50
Min, Max	15.1, 33.3	13.7, 34.5	13.7, 40.1	13.7, 40.1
Baseline Height (cm)				
n	88	84	84	254
Mean (SD)	162.57 (11.52)	163.82 (10.13)	163.43 (10.42)	163.93 (10.78)
Median	162.60	165.10	162.60	162.85
Min, Max	137.2, 185.4	146.1, 190.5	135.0, 195.6	135.0, 195.6
Baseline Weight (kg)				
n	88	84	83	253
Mean (SD)	62.76 (12.77)	70.00 (14.65)	67.28 (14.12)	66.65 (14.13)
Median	60.55	69.20	64.90	66.70
Min, Max	34.0, 96.2	41.7, 108.0	45.4, 106.1	34.0, 108.0
Safety Population Flag				
Y	88 (100.0%)	84 (100.0%)	84 (100.0%)	254 (100.0%)
Footnote				



Azure Data Platform

Data Lake Storage is a scalable and secure data lake for high-performance analytics workloads. This service manages multiple petabytes of information while sustaining hundreds of gigabits of throughput. The data can have these characteristics:

- Be structured, semi-structured, or unstructured.

- Come from multiple, heterogeneous sources like logs, files, and media.

- Be static, from batches, or streaming.

Delta Lake is a storage layer that uses an open file format. This layer runs on top of cloud storage such as Data Lake Storage. Delta Lake is optimized for transforming and cleansing batch and streaming data. This platform supports these features and functionality:

- Data versioning and rollback.

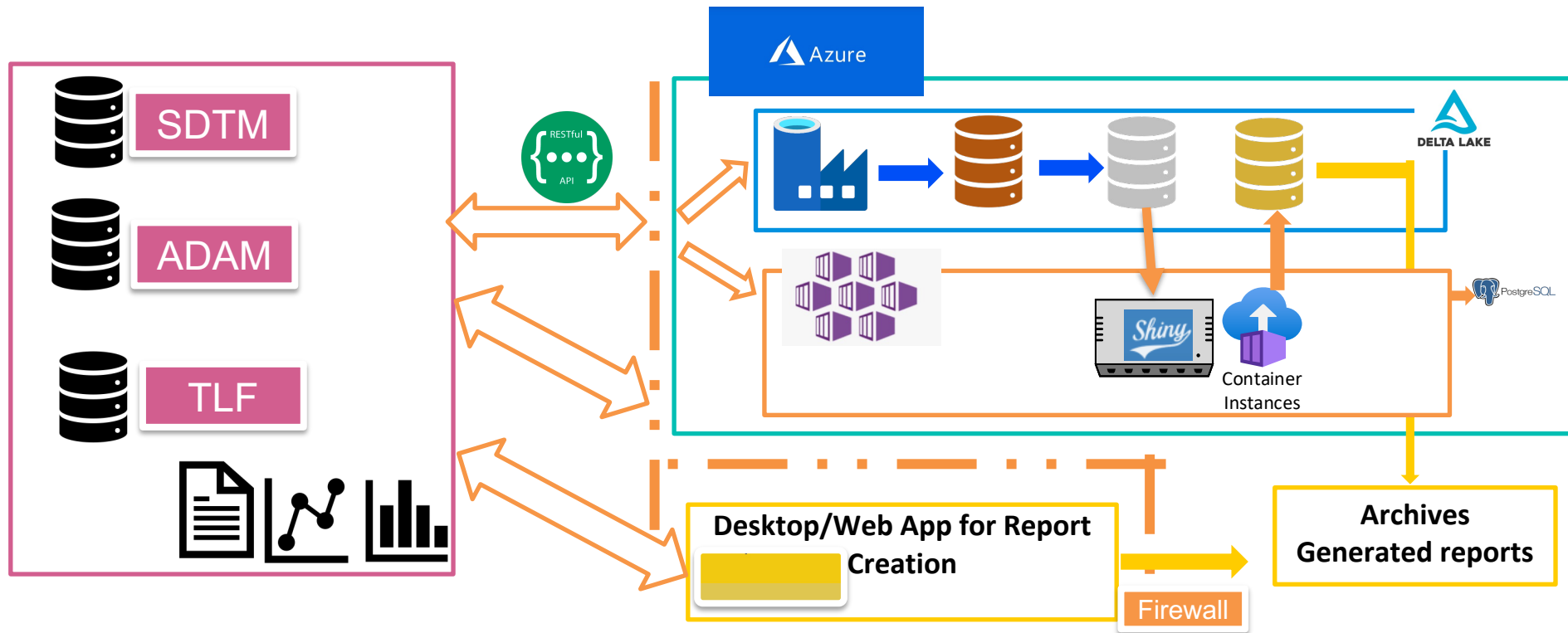
- Atomicity, consistency, isolation, and durability (ACID) transactions for reliability.

- A consistent standard for data preparation, model training, and model serving.

- Time travel for consistent snapshots of source data. Data scientists can train models on the snapshots instead of creating separate copies.



Architecture



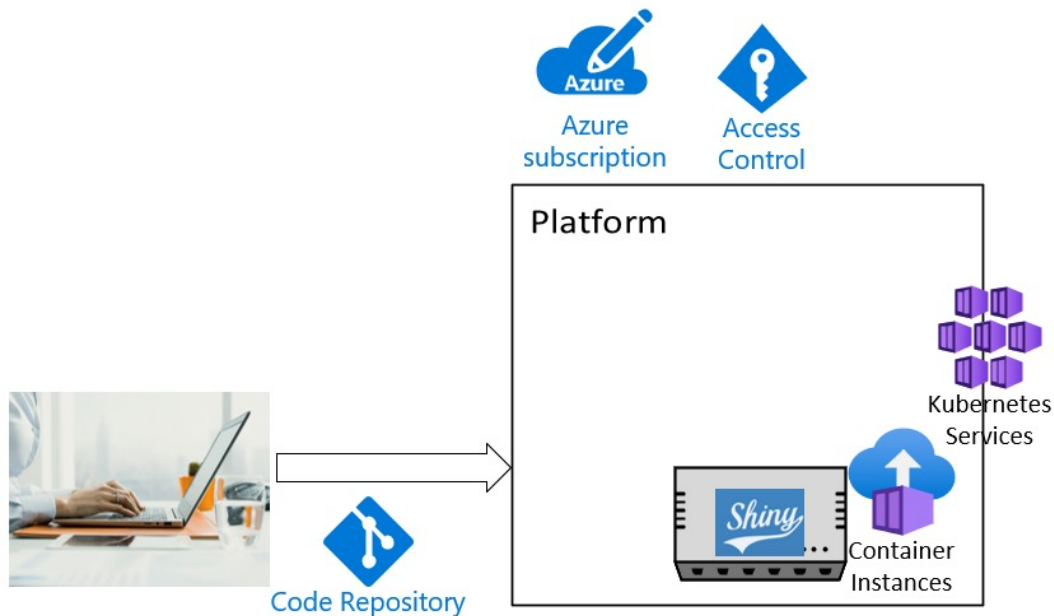


Visualization

Data Pipeline will be established to get the data from source systems

Data Scientists use local R-Studio set up on their local machines to develop shiny applications

Programmers publishes their code to the Platform.





Product Roles

Data Analyst (DA) - Data Analysts gather data from various sources and review and interpret it using data analysis tools to provide meaningful information and insights to help businesses make better-informed decisions. This could be decisions about any aspect of business, for example investments, cost-savings, pricing, hiring, operations or scheduling - all of which can help to create a competitive advantage in the marketplace.

Data Scientist (DS) - Data Scientists utilize their analytical, statistical, and programming skills to collect, analyze, and interpret large data sets. They use this information to develop data-driven solutions to business related challenges. Data scientists have a wide range of technical competencies including: statistics and machine learning, coding languages, databases, and reporting technologies.

Data Steward (DS) - Data Stewards coordinate quality, security, and maintenance of data. They define data elements and establish policies and procedures related to the collection and accuracy of data and perform tests. Data Stewards ensure to maintain sufficient data quality so that data can support any business process.

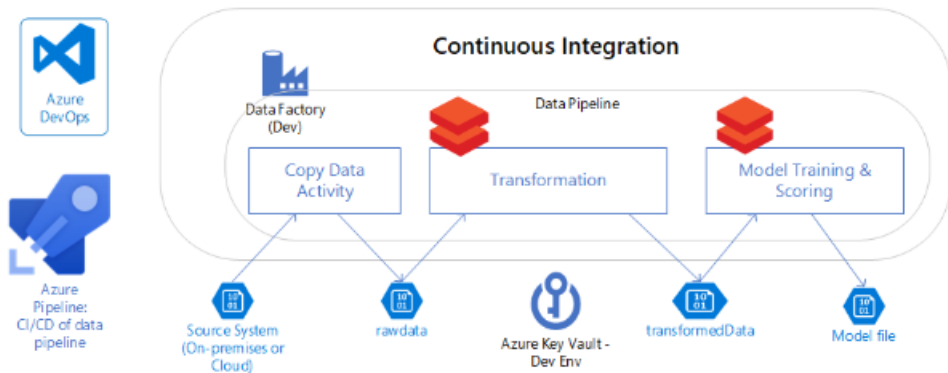
Product Owner (PO) - The Product Owner (PO) is a member of the Agile Team responsible for defining Stories and prioritizing the Team Backlog to streamline the execution of product priorities while maintaining the conceptual and technical integrity of the Features or components for the team.

Security Engineer (SE) - A Security Engineer owns initiatives related to security of Platform that includes especially Infrastructure, Data and GxP requirements. They identify and mitigate security issues, vulnerabilities, and misconfigurations by applying in-depth knowledge of operating systems, infrastructure, data and Azure cloud provider services.

Site Reliability Engineer (SRE) - Site Reliability Engineers (SREs) are responsible for keeping all business respectively user-facing services and other production systems running. SREs are a blend of pragmatic operators and software engineers that apply sound engineering principles, operational discipline, and mature automation to our environments and the codebase.



Tools we use





**The Global Healthcare
Data Science Community**

Contact Channels

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