CTCG FAQ

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CTIS Information Day Webinar

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CTCG FAQ UPDATE

Objective:

- Expand the CTCG FAQ with additional questions raised by sponsors
- Improve clarity on sponsor obligations and Member States' expectations
- Reduce the volume of ad-hoc queries to the EU clinical trials network, including EMA

Scope & Progress:

- Exercise launched in November 2025
- Questions from CTIS service desk discussed in the External Best Practice Subgroup were reviewed **(approx.** 100 questions)
- All questions raised during EMA events, with Member States' support, were assessed (**approx**. 1000 questions)

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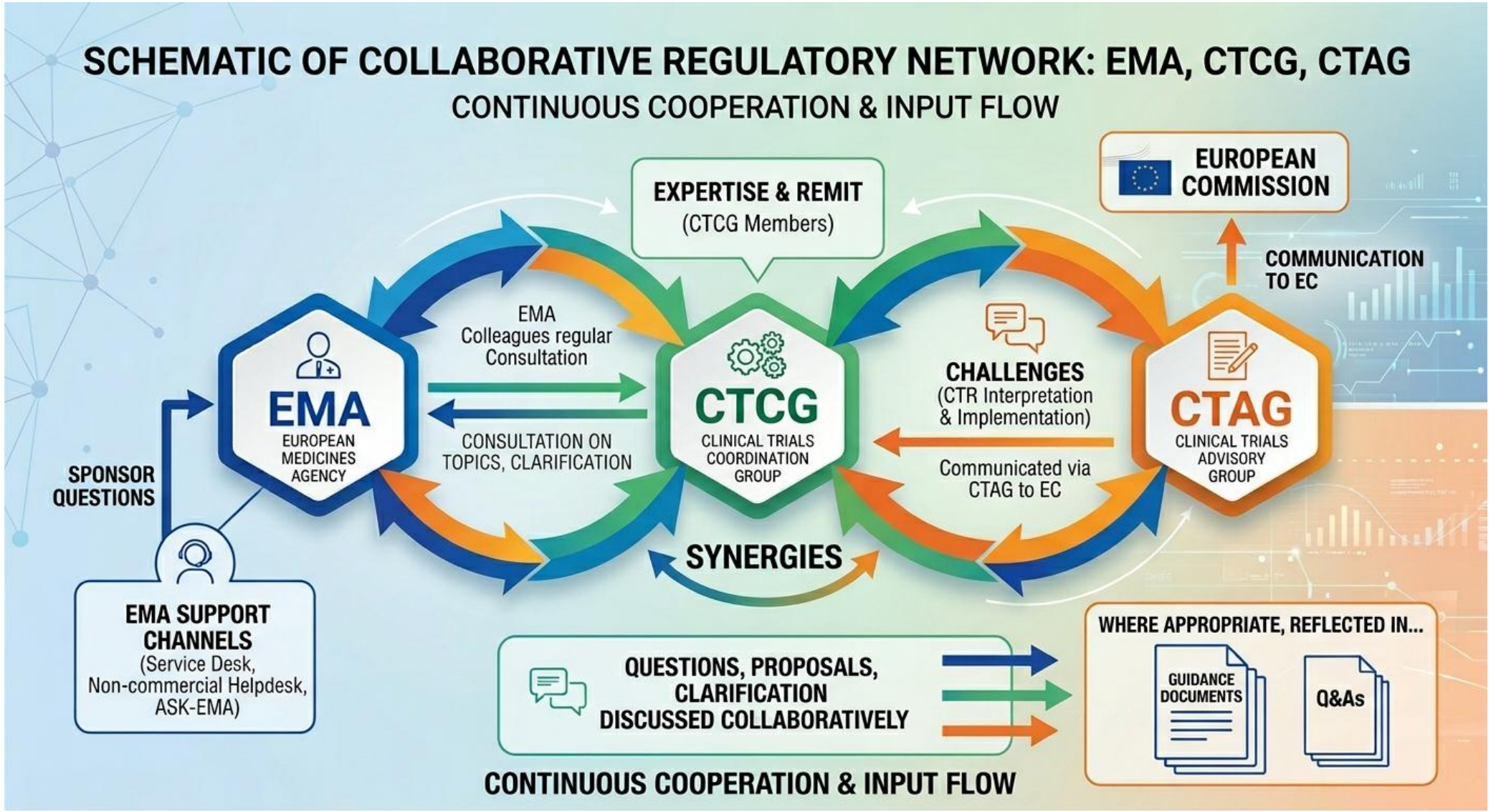
Interaction on Guidance



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Different sets of information:

CTCG FAQ: Expectations on documents to be provided in a clinical trial applications, follow-up procedures or notifications

Sponsor Handbook FAQ:

CTIS related aspects

CTAG Q&A:

Aspects concerning legal interpretations

Some overlap between these different documents cannot be fully avoided

Harmonisation / avoidance of conflicting information is a clear intention

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Frequently asked questions related to Clinical trials submitted under the Regulation EU 536/2014

Introduction

These frequently asked questions (FAQ) were submitted to the European Medicines Agency (EMA) through different channels. They were addressed by the Clinical Trials Coordination Group (CTCG) in collaboration with the European Medicines Agency Clinical Trials Systems and Clinical Trials Transformation workstreams.

This document provides clear and concise answers to common questions, supporting sponsors in the efficient conduct of clinical trials across Europe. It is a living resource and will be regularly updated to include new questions and answers as additional areas requiring clarification are identified.

https://www.hma.eu/fileadmin/dateien/CTCG_FAQ_v2_final_clean.pdf

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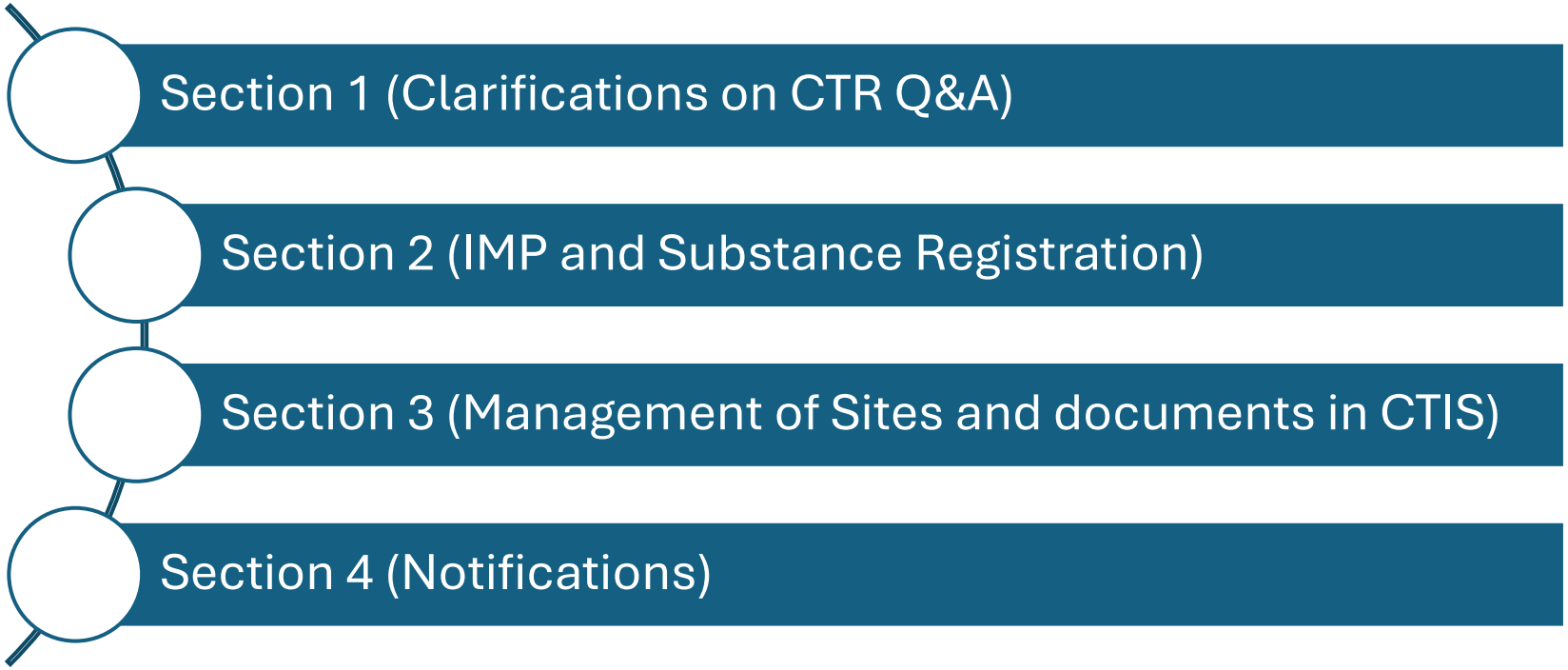
CTCG FAQ – Version 1



17 questions and answers in total

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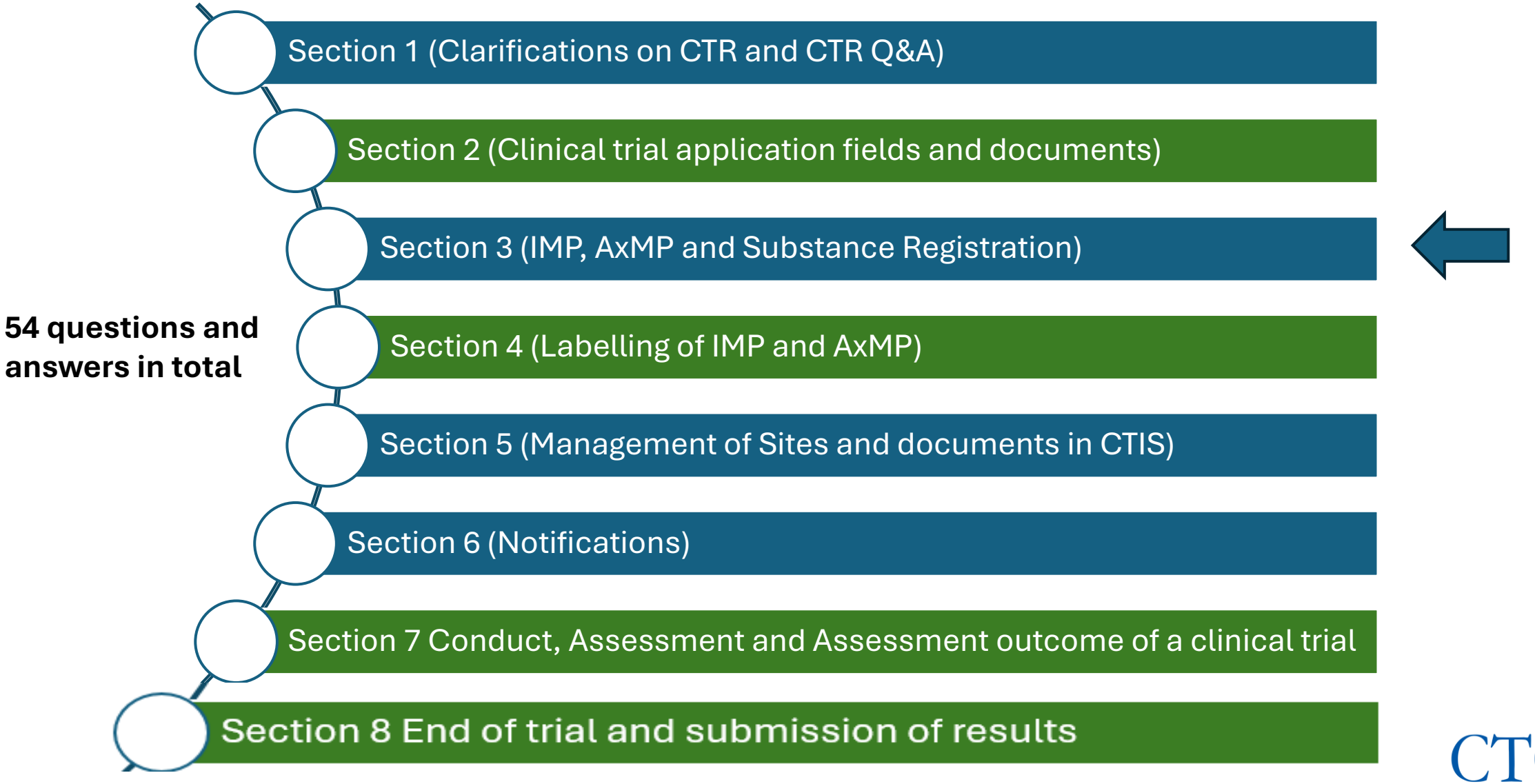
CTCG FAQ – Version 2



54 questions and answers in total

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Highlights:

- **Expanded section 3** with the Quality-related questions discussed at the Quality CTCG Assessors' Roundtable (ART)
    - Strong support from Quality assessors
    - Many aspects from different fora (e.g. Walk In Clinics) screened for integration to allow better identification of information as compared to screening of event recordings

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XEVMPD and CTIS registration of IMPs

Section 3

Introduction of **structured scenarios** (for Clinical vs commercial batch) for product registration in CTIS / XEVMPD clarifying when a product should be considered:

- Authorised
- Authorised with modifications
- Not authorized

and what the expectations on quality documents are.

b) Product that has a MA in the EU. The batch to be used in the clinical trial is a clinical batch (not released under the EU MA):

A:

XEVMPD	CTIS	Documentation required
Registration is not required, despite that the product to be used is not considered authorised	Register the IMP as authorised – modified, including a clarification that a clinical batch is used	IMPD or simplified IMPD, as applicable. The IMPD should describe the differences compared to the authorised drug product, preferably in a tabulated form.

c) Product that has a MA in the EU. The product to be used in the clinical trial is modified only with changes related to primary packaging:

A:

XEVMPD	CTIS	Documentation required
No registration required; the product remains authorised	Register as authorised – modified. Note: changes to primary packaging constitute a modification, whereas re-labelling alone does not.	Simplified IMPD GMP documentation related to the manufacturer of primary packaging is needed

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Highlights:

- **Section 6 Notifications**
- Updates on notification requirements, e.g.
  - No recruitment at trial sites
  - Restart after temporary halt
  - UE and USM notification requirements
  - Serious Breach timelines

- **New Section 7**
  Conduct, Assessment and Assessment outcome of a clinical trial

  - RFI
  - Alignment Part I and Part II
  - AddMS
  - nSM and SM submission expectations
  - Appeals
  - Supply of IMP/AxMP

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Highlights:

- **Section 8**

End of trial and submission of results

- Ad hoc RFI and/or corrective measure after End of Trial
- Expectations on Sponsor to actively screen CTIS after EoT
- Summary of results / layperson summary

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CTCG FAQ NEXT UPDATES

CTCG FAQ should be considered a working document

- **Clinical trial environment continuously screened for recurring questions and needs for clarification**
- **Feedback provided at different settings (e.g. Walk-in Clinic) will be followed up to identify most relevant aspects and will then be considered for clarification in the most appropriate document**
- **Document will be updated accordingly, when new aspects arise or current topics need to be updated/clarified**

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Thank you for your attention

Thank you to Cátia Goncalves for the support in the creation of the slides

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