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PEER REVIEWED

Envisioning eConsent Success (Part I): Measuring Operational Impacts at Clinical Trial Sites

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The electronic informed consent (eConsent) working group of The League, a Florence Healthcare initiative, has developed a high-level framework for defining and measuring the impact of eConsent usage at clinical trial sites. This article outlines key success indicators, relevant metrics, and practical steps the industry can take to begin assessing the real-world impact of eConsent on site operations. As eConsent adoption matures, this high-level framework can evolve into a more complex key performance indicator (KPI) infrastructure. A companion article in this same issue, "Envisioning eConsent Success (Part II): Laying Out a Global Interoperability Blueprint for eConsent," focuses on a technology-agnostic integration blueprint that considers both sponsor-deployed and site-owned systems, and prioritizes both operational feasibility and reduction of duplicate workflows at study sites.

Background

In the clinical trials industry, adoption of eConsent is often reported as being in the range of 50% to 75%.{1–3} The stated benefits of eConsent typically include improved patient engagement and operational efficiency.{3} The eClinical technology landscape is both vast and complex, with more than 60 vendors offering solutions, which also suggests high adoption and a saturated market.{4} However, anecdotal evidence suggests that these adoption numbers may be inflated; it is commonly reported by panelists at industry conferences, in virtual roundtables, on webinars, and among the eConsent working group members that the rate of real-world experience with eConsent is actually very low.

Further, several large, multi-stakeholder eConsent initiatives highlight the limited guidance available for effective implementation as well as misconceptions and disconnects in the industry,{5,6} also suggesting that adoption is lower than reported. However, there has been U.S. Food and Drug Administration (FDA) support for eConsent usage since 2016,{7} and more recent global regulatory guidance and support,{8,9} so no obvious regulatory hurdle is preventing industry adoption.

The reality is that eConsent adoption and implementation remain fragmented.{10,11} The European Forum for Good Clinical Practice (EFGCP) explains this fragmentation as follows: "There is no one size fits all eConsent: each indication, each study, each study population, each site, and each participant might have different needs."{6}

Sponsor eConsent usage and vendor selection vary by study phase, size, and geography, as well as sponsor/contract research organization (CRO) preference and various other factors. Sites considering purchasing or using sponsor-provided eConsent must consider their existing technology infrastructure, staff experience, sponsor relationships, institutional review board (IRB) policies, and evolving regulatory requirements, such as the validation requirements in the ICH E6(R3) guideline for Good Clinical Practice (GCP) from the International Council for Harmonization.

Sites also report that they sometimes receive sponsor-pushback on the use of eConsent. All stakeholders face hurdles such as information technology (IT) review time, change management,

platform cost, and concerns about integrating eConsent into existing workflows.{12} Sponsors and CROs face similar challenges to adoption and implementation, and must also consider global regulatory compliance to ensure consistency across study sites.{11,13} These challenges have blunted eConsent adoption and implementation and resulted in fragmented usage of the many vendors across studies in the industry.

As a result of the industry fragmentation, there is no standard measure of eConsent success. Many assessments of eConsent success focus on participant-centric metrics, like comprehension, satisfaction, and retention.{14–17} These metrics are critical to understanding the participant experience, but do not evaluate the operational impact and burden at the site level, where implementation and usage are critical to any measure of participant success.

The industry lacks a unified approach to understanding and assessing site impact, which directly affects eConsent adoption and success. The eConsent working group of The League wanted to address this industry gap, and as such worked to develop a high-level framework for defining and measuring the impact of eConsent usage at clinical trial sites.

Deployment Model Definitions

The users of eConsent systems are always site staff and participants, but there are two different models for which stakeholder provides the system: site-owned or sponsor-deployed. The deployment model being used in a specific setting and/or for a specific trial affects the operational impact of the systems in play, and so must be defined and understood first.

Site-Owned: A site may invest in an eConsent system as a platform for use across its study portfolio. This system would be managed and supported by site staff, integrated into site standard operating procedures (SOPs), work instructions, and IRB approval processes and used across many studies contracted by various sponsors or CROs. Sites are responsible for the informed consent process and should be able to conduct this process using any tool that complies with all regulatory requirements, but sponsors/CROs have an obligation to confirm that the site-owned system is fit for purpose, validated, and compliant with data privacy standards and other regulations. The sponsor and IRB would also need to approve any site-created study content used

in the system. In some cases, sponsor regulatory or logistical concerns result in the parties foregoing eConsent usage.

Sponsor-Deployed: A sponsor/CRO may contract with an eConsent vendor to provide eConsent to sites for a specific study. This system would be managed and supported by the sponsor/CRO, with access provided to site staff for the study. Sites and principal investigators (Pis) retain ultimate responsibility for informed consent oversight and documentation, so sites may need to update their consent processes or SOPs to include eConsent as an option. Site IRBs may need to develop a new approval process for eConsent used in this situation. Sites may need to determine how to satisfy their own regulatory requirements for consent documentation and record retention when using sponsor-deployed eConsent for a study.

In both deployment models, it is important to remember that consent methods for a study will likely still include *both* electronic and paper consents, as participant preference may vary across individuals and study timepoints, and may even include both electronic and paper consents at different time points for the same participant. The chosen consent method can vary depending on the participant's preferences, technology access and fluency, and convenience at any given time. Hybrid workflows require sites to maintain and reconcile eConsent and paper tracking and final document storage procedures, which will vary in complexity depending on the deployment model and can increase the site's administrative burden.

Deployment Model Implications

The operational impact of eConsent on study stakeholders can differ depending on whether the system is site-owned or sponsor-deployed, and understanding those differences is critical to planning integrations and considering success metrics. In Table 1, the working group documented the details and implications of eConsent across different dimensions for each deployment model, primarily from the site perspective.

Table 1: Details and Implications of eConsent in Different Deployment Models

	Site-Owned	**Sponsor-Deployed**
Purchaser	Site	Sponsor/CRO
Study usage	All/most site studies across many sponsors/CROs	Single study usage (possibly across multiple studies from the same sponsor, or from different sponsors/CROs if the same vendor is chosen)
System Training	Consistent across studies; internal training reused	System differs by study; new training each time
Workflow Alignment	Tailored to site SOPs and existing systems	May require parallel or duplicative processes and/or changes to SOPs or new SOP creation; may cause a workflow conflict when a site-owned eConsent is in place
Tech Support	Managed by site/vendor; more direct and expedient communication and support	Dependent on sponsor/vendor; point of contact may be unclear (sponsor, CRO, vendor)
System Content	Site is responsible for creating/uploading consent documents and must coordinate with sponsor if content needs to be approved; site must ensure local IRB and institutional requirements are met	Sponsor may load consent documents/content in the system but must coordinate with sites to ensure template documents are customized for the site and any local language and IRB requirements are met
Version Control	Site staff control, maintain, and update the consent version in a repeatable process when protocol amendments occur or consent form changes are required	Sponsor may need to create/load the newest IRB-approved version in the system; delays in getting new versions active in the system can force sites to revert to paper or delay enrollment
IRB and Regulatory Considerations	Sponsor may want to approve usage of the tool; sponsor and IRB must approve any study content the site creates for use in the system	Site needs to ensure SOPs support use of this tool and that consent process requirements are satisfied; IRB needs to review the patient interface; adds a compliance risk by having different process for studies using this tool rather than

		the standard site SOP
IT/Security/Data Privacy Review	Centralized validation and data privacy controls	New IT/security and data privacy review needed for each study/vendor
Cost Model	Higher upfront cost; potential long-term return on investment (ROI)	No direct cost to sites, but higher hidden labor burden and change management barrier
Audit Readiness	Unified document access and version control	Variability across studies; fragmented tracking
Integration Strategy	Integrations to other site systems would be repeatable, but must be funded by the site; integrations to sponsor systems unlikely to be supported	Integrations to other sponsor systems might make sense and would be funded by the sponsor

Note: This framework is designed to help stakeholders understand the implications of the different deployment models and is not a recommendation for or against either deployment model.

Defining Success for All Stakeholders

The first step in defining success metrics is understanding what success means for the various stakeholders involved in the process, regardless of deployment model. In Table 2, the eConsent working group analyzed the process of using eConsent to document a draft list of success criteria. Of course, this list is not exhaustive and each stakeholder should consider their own process and unique success criteria. This framework intentionally omits participant-facing metrics to focus on the site operational experience for all formats of eConsent.

Table 2: Stakeholder Perspectives on Operational Success

Stakeholder	Success Criteria
Clinical Research Coordinator (CRC)/PI/ Regulatory Staff	● Reduction in consent-related deviations due to technology features and support, no technology-related deviations ● Decrease or no increase in duplicate data entry or manual process steps

	● Ability to manage hybrid consent models where some participants may require paper consent ● Clear SOP alignment ● Timely updates to consent content in the system when protocol amendments or consent form changes occur ● Efficient process for making changes to sponsor-driven eConsent documents when required by the local IRB or research institution ● Smooth reconsenting process and version management with access to a participant's consent history ● Ability to manage clinical research associate (CRA)/monitor access ● Adequate technical support as needed ● Support for IRB submission ● Potential for integrations (IRB, clinical trial management system [CTMS]) ● Immediate access to executed consent records, metadata, and audit trails, with the ability to reconstruct the consent process during audits ● Supports ownership and oversight of the complete consent process and consent process documentation (patient comprehension, understanding, time to review, voluntary participation, etc.)
IRB	● Must support an appropriate consent process ● System meets regulatory expectations for transparency, participant comprehension, and record integrity ● Adequate version control process ● Timely updates to consent content in the system when protocol amendments or consent form changes occur ● Appropriate patient identity verification process ● Supports the complete consent process
Senior Leadership	● Clear cost-benefit ratio and ROI ● Central oversight for study enrollment progress and quality audits of consent process ● Audit/inspection risk reduction
System Owner/ Information Security/IT	● Compliant with the ICH guideline for GCP and a validated system according to 21 CFR Part 11 of the *Code of Federal Regulations* in terms of meeting "fit-for-purpose" standards ● Meets security and data privacy standards ● Appropriate access control

	● Validation process support
CRA/Monitor	● Appropriate system access ● Access to all consent forms
Sponsor/CRO	● Alignment with sponsor SOPs ● Allows for global alignment across sites ● Continuous access for sites to consent participants with the current consent form version ● Access to consent data for monitoring and audits ● Meets data privacy and security standards ● Reduces version deviations and supports faster time for reconsent completion ● Potential for integrations ● Compliant with the ICH guideline for GCP and validated under 21 CFR Part 11 as a system that meets "fit-for-purpose" standards ● Audit/inspection risk reduction
eConsent Vendor	● High site and participant adoption ● Low support burden ● Successful integrations to reduce manual work

Core Success Indicators for eConsent

Rather than suggesting complex KPIs, the working group recommends focusing on a small set of qualitative and directional measures, based on the success measures defined above. Since consent operations primarily occur at the site regardless of the deployment model, these metrics are site-centric but apply to both deployment models.

These indicators are designed to help sites, sponsors, and vendors assess the operational effectiveness of eConsent systems. The aim is to gather directional data to identify burden and track improvement over time, especially considering there is a learning curve for any new process, eventually creating benchmarks. Note that it may be important to differentiate some of these metrics by therapeutic area since different diseases, their stages, and patient populations

may impact the usage of eConsent. This framework intentionally omits participant-facing metrics to focus on the site's operational success indicators.

Adoption and Access

- % of consented participants using eConsent vs. paper
- % of studies offering eConsent as an option
- % of consents completed remotely vs. in-person

Workflow Impact and Operational Efficiency

- Site-reported time savings on administrative burden (e.g., paperwork, scanning, version tracking, duplicate documentation)
    - ✓ Assess regularly since it may take time to realize any benefits as the system is adopted and familiarity grows
- Average onboarding/training time for staff
    - ✓ Time needed for training on system updates
- Number of helpdesk tickets and IT escalations
- Time from IRB approval of a consent form to it being active in the eConsent system (Including time for site-specific updates and system changes that require sponsor action)

Data Quality and Compliance

- Number and type of consent deviations (vs. paper consent)
- Sponsor/monitor access delays or issues
- Audit/inspection access delays, issues, or findings
- IRB review/approval friction with eConsent forms or systems
- Ability to manage hybrid consenting using both paper and electronic forms
- Software usability for participants (complaints, failures, successes)
- Alignment with consent SOPs, ability to support consent process documentation

System Fragmentation

- Number of different eConsent platforms used at the site
- Integration with CTMS, IRB portals, or electronic investigator site file
- Staff-reported duplication of effort due to system fragmentation (Y/N or score)

Staff Satisfaction and Burden

- Overall ease of use rating for different site roles (PI, CRC, regulatory staff)
- Perceived impact on workload compared to paper (better/worse/same)
- Confidence in system compliance and audit readiness (Y/N or score)

Conclusion

As eConsent becomes more widely adopted, it's critical that we measure not only how it supports participants but also how it impacts the operations of the research sites tasked with implementing it. This article outlines a site-centered definition of success that applies to all stakeholders and moves beyond patient-facing metrics to include workflow efficiency, data quality, compliance readiness, and system burden. Both site-owned and sponsor-deployed eConsent platforms can be assessed using the suggested qualitative and directional core success indicators.

This framework is just a starting point, and the authors encourage all stakeholders to incorporate additional metrics as appropriate. Once stakeholders have a baseline understanding of operational impact, they can move into more quantitative measures. Ultimately, defining and measuring what matters most to sites is key to improving adoption, reducing burden, and realizing the full promise of eConsent in clinical trials.

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Envisioning eConsent Success (Part II): Laying Out a Global Interoperability Blueprint for eConsent

Amanda Zenere; Amber N. Hood, DFS, MS, CPIA, CIP; Candida Barlow, PhD, MSN, CRN-BC, RN; Catherine Gregor, MBA, CCRP, CCRC; Istvan Feteke; Kamila A. Novak, MSc; Katherine Leibowitz, JD; Megan Solomon, LPN; Spencer Phelps; Andrea Bastek, PhD

The electronic informed consent (eConsent) working group of The League, a Florence Healthcare initiative, has developed a clear, practical framework that defines the value of integrating eConsent systems with key eClinical technologies. In the companion piece to this article, "Envisioning eConsent Success (Part I): Measuring Operational Impacts at Clinical Trial Sites," the group defined the different deployment models for eConsent and outlined key stakeholder success measures for using these systems. This article focuses on a technology-agnostic integration blueprint that considers both sponsor-deployed and site-owned systems, and prioritizes both operational feasibility and reduction of duplicate workflows at study sites

Background

The decision to purchase eConsent software often depends on the number of studies that will utilize the platform. Implementing the platform system-wide, across many studies, helps organizations justify the cost of the system and implementation as well as of the disruption that comes from implementing a new tool and process. On the other hand, buying and/or implementing a system for a single study can be more expensive than planned when considering the cost of disruption. As noted in Part I, these challenges have blunted eConsent adoption and implementation and resulted in fragmented usage of the many vendors across studies in the industry. This fragmentation makes it challenging to integrate eConsent with other eClinical systems and creates duplication, delays, and confusion, particularly at the site level.

As defined in Part I, the users of eConsent systems are always site staff and participants, but there are two different models for purchasing and deploying the system: site-owned and sponsor-deployed. Each deployment model has its own economic factors to consider.

Deployment Model Implications

The investment required by sponsors to implement eConsent, including system validation, staff training, process modification, change management, and ongoing support, may be justified when it can be leveraged across multiple studies, where it is most likely to deliver a return on investment (ROI) from labor savings, quality improvement, or timeline acceleration.

Conversely, sites with larger or sustained research portfolios may derive greater long-term value from a site-owned platform, particularly where standardization across studies and sponsors can be achieved. Similar considerations apply to sponsors; accordingly, the economic rationale for either model is primarily determined by anticipated study volume and the ability to leverage implementation and change management costs across future use. There is no "one-size fits all" approach for how to consider all of these factors.

Beyond ROI, the overall operational impacts of eConsent on study stakeholders can differ depending on whether the system is site-owned or sponsor-deployed, and understanding those differences is critical to planning integrations and considering success metrics (see Table 1 in Part I).

Key Integration Objectives

The goal of integration is to ensure that eConsent data and documents can flow securely and automatically between systems to improve efficiency and reduce staff burden and quality errors. Potential benefits of system integrations include:

- Eliminating duplicate data entry and manual document uploads
- Using consent data as a gate/trigger for other systems, such as electronic patient-reported outcomes (ePROs) or interactive response technology (IRT)
- Reducing compliance risk via audit-ready consent documentation and version control
- Enabling real-time oversight for site leaders, monitors, and sponsors

While the core integration goals of eConsent platforms are consistent among users, the strategy for achieving interoperability differs significantly depending on whether the eConsent system is owned by the site or deployed by the sponsor.

Sponsor-deployed systems typically operate as stand-alone platforms with minimal integrations to site systems, which is understandable given that they are deployed by an external entity for a single study. Sponsor-deployed systems cause fragmentation for sites because different sponsors provide different platforms and sites have their own consent processes for situations when an eConsent tool is not provided by a sponsor.

Lack of interoperability with site systems creates duplicate effort (ex: manually tracking consents on a paper or digital log in the investigator site file [ISF] and/or in the clinical trial management system [CTMS]). These systems also require a new process for sites to maintain audit-ready documentation since they do not own the system. Sites are responsible for the consent process and documentation to ensure regulatory compliance, so this fragmentation can be particularly disruptive.

Site-owned systems certainly avoid some of these problems, and allow for reusable integrations, but require upfront system investment and additional investment for integrations. This can be a challenge for small sites and sites with a low number of studies.

Since both site-owned and sponsor-deployed models will likely co-exist in the industry for some time, this working group included considerations and limitations of both models in this framework. In both models, the ROI should be estimated for any proposed integration. Increased site staff efficiency and reduced compliance risk will likely be the value drivers of an eConsent integration, and can have a significant impact over time.

Core Systems for Integration

To support efficient trial operations, consent data and documents can integrate with the broader clinical trial technology stack to reduce duplicate data entry and manual document downloads/uploads, and to ensure consistency and compliance. Tables 1 and 2 outline the key systems that could connect with eConsent platforms and the purpose of each integration. The scope of integrations will vary between site-owned and sponsor-deployed eConsent systems.

Table 1: Site-Owned Integrations

System	Integration Purpose
Electronic Health Record (EHR)	Retrieve participant identity and demographics needed to enter a participant in the eConsent system; Record consent visit data; Store the final signed consent form (depending on site standard operating procedures)

eISF/eRegulatory	Maintain master institutional review board (IRB)-approved consent version; Manage version expiration dates; Populate consent logs with participant ID, consent version, and date of consent
Participant Source Binders	Store final signed participant consents; Provide access during subject or monitoring visits
CTMS (Site-Owned)	Track participant consent status, version, and date; Track sub-study consents; Track withdrawals; Manage reconsent requirements; Link to enrollment and visit workflows; Enable consent-dependent actions
Payment Systems (Site-Owned)	Trigger site and participant payments based on successful consent completion
Training/Learning Management Systems	Gate access to eConsent platforms until site staff complete protocol or system-specific training and are delegated appropriately
IRB Portal (Local)	Retrieve approved consent versions; Deactivate old versions when new version is approved to prevent version errors; Track expiration dates
Other Participant-Facing Workflows	Include W9s, release of records forms, future use consent forms, or post-trial communication preferences in the same system to streamline workflows for site staff and participants

Table 2: Sponsor-Deployed Integrations

System	Integration Purpose
Electronic Trial Master File (eTMF)	Centralize storage of all master consent versions (including country/site-specific); Store central IRB approval records; Store site-specific IRB/sponsor-approved consent versions (including country/site-specific)
CTMS (Sponsor-Owned)	Track consent version and dates for participants; Monitor compliance with version requirements; Track sub-study consents; Track withdrawals; Enable oversight and tracking

Electronic Data Capture (EDC)	Enter consent date and version automatically before unlocking further data entry
IRT/Randomization and Trial Supply Management (RTSM)	Block or allow randomization and investigational product shipping based on verified consent status/version and date
ePRO/Electronic Clinical Outcome Assessment (eCOA)	Validate participant consent before enabling access; Track consent version/date for sub-studies or secondary endpoints
Payment Systems (Sponsor-Owned)	Trigger site and participant payments based on successful consent completion
Training/Learning Management Systems	Gate access to eConsent platforms until site staff complete protocol or system-specific training and are appropriately delegated
IRB Portal (Central)	Retrieve approved consent versions; Deactivate old versions when new version is approved to prevent version errors; Track expiration dates
Data and Safety Monitoring Board (DSMB)/ Adjudication/Imaging	Send consent version and date for safety adjudication or imaging workflows; Track sub-study consents to ensure correct imaging workflows are completed
Central Lab, BioSample, and Imaging Systems	Send consent data to facilitate sample/CT/X-ray/MRI/Fluoro collection; Support eligibility checks when applicable and streamline data/file transmission; Include withdrawal tracking if applicable

Recommended Core Data Elements

To ensure eConsent platforms function as part of a connected clinical trial ecosystem, system connections must be built on reliable, standards-based integration methods. Whether site-owned or sponsor-deployed, eConsent systems should, at a minimum, offer the fields listed in Table 3 as required discrete data elements.

Table 3: Required Discrete Data Elements

Data Field	Purpose
Participant ID	Unique participant linkage across systems
Consent Version	Audit-ready version tracking; Facilitate re-consent workflows
Date of Consent	Enrollment tracking; Integrated system workflow trigger/eligibility gating
Investigator Signature Date	Verification and compliance
Consent Method (e.g., remote/in-person)	Operational tracking
Consent Status	Enrollment tracking; Reconsent workflow trigger
Health Insurance Portability and Accountability Act (HIPAA) Authorization Date	Verification and compliance, where applicable
Participant Copy Provided (Y/N)	Regulatory requirement
Date of Withdrawal of Consent	Tracking early exits from participation
Sub-Study Consent (Y/N)	Enrollment tracking; Integrated system workflow trigger
Post-Trial Access (Y/N)	Gates post-trial communications
Future Research Consent (Y/N)	Gates future contact workflows

While this list is not exhaustive of the desired data for an eConsent system to collect or transfer via an integration, it provides a foundation for common datapoints that all systems should include. The European Forum for Good Clinical Practice eConsent Initiative has included similar datapoints in their Glossary of eConsent terms Operational Aspects, describing key aspects related to operational management.{1} It is important to note these suggested data fields and operational aspects of eConsent are often also applicable in the traditional paper consent process. Since the consent process will often be hybrid, using both paper and eConsent, it is critical to consider how these datapoints will be captured and recorded for paper consents, and how that data can be incorporated in the system integrations to avoid having two completely separate processes.

Integration Challenges and Considerations

eConsent integration challenges vary depending on whether the system is site-owned or sponsor-deployed. Sponsor-deployed systems introduce more variability across studies, but integrations with other study systems can reduce the workflow transitions, logins, and data entry points for the sites working on those studies. Since that is a downstream impact, and because there is so much variability in sponsor/CRO technology stacks from study-to-study, the ROI of building integrations can be hard to justify.

Site-owned systems offer consistency across studies at the site but require significant initial investment for licensing, implementation, and integrations. These upfront costs can be difficult for sites to manage due to resource constraints. Many site systems are not built with open application programming interfaces (APIs) and sites often do not have the technical capacity to support integration efforts. The resource and technical constraints at sites can make it hard to justify system integrations despite the long-term efficiency gains.

Conclusion

eConsent is a tool that can eliminate a significant amount of paper and drive efficiency in the clinical trial industry. However, the efficiency and benefits of an eConsent system are limited by the technology ecosystem where it is deployed. Without seamless integration into other systems that support clinical trials, eConsent becomes another siloed tool that adds new friction. Key challenges to widespread integration are varying adoption and deployment models, hybrid workflows and lack of resources for integration efforts.

This integration blueprint outlines a practical, system-agnostic approach to eConsent interoperability that works across both site-owned and sponsor-deployed models. If sites and sponsors can focus on logical system connections for their deployment model, stakeholders can begin to reduce redundancy, improve data flow, and enhance oversight. If vendors can focus on using standard data elements and building open, well-documented APIs and flexible integration endpoints, the burden of integration will decrease. By measuring gains in efficiency, the value of these integrations can be proven over time.

With industry collaboration, we can move toward a future where eConsent systems are not standalone platforms, but connected, compliant, and supportive of both participant, site, and sponsor needs.

Reference

1. The European Forum for Good Clinical Practice eConsent Initiative Glossary of eConsent. 2024. https://efgcp.eu/public/EFGCP%20Glossary%20of%20eConsent%20Terms.pdf

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