



MEDIBRIDGE CONNECT • TRIAL RUN SOP
UNIFIED DIGITAL ECOSYSTEM

TRIAL PLAN · PROOF OF CONCEPT ON THE CLIENT'S OWN SYSTEMS

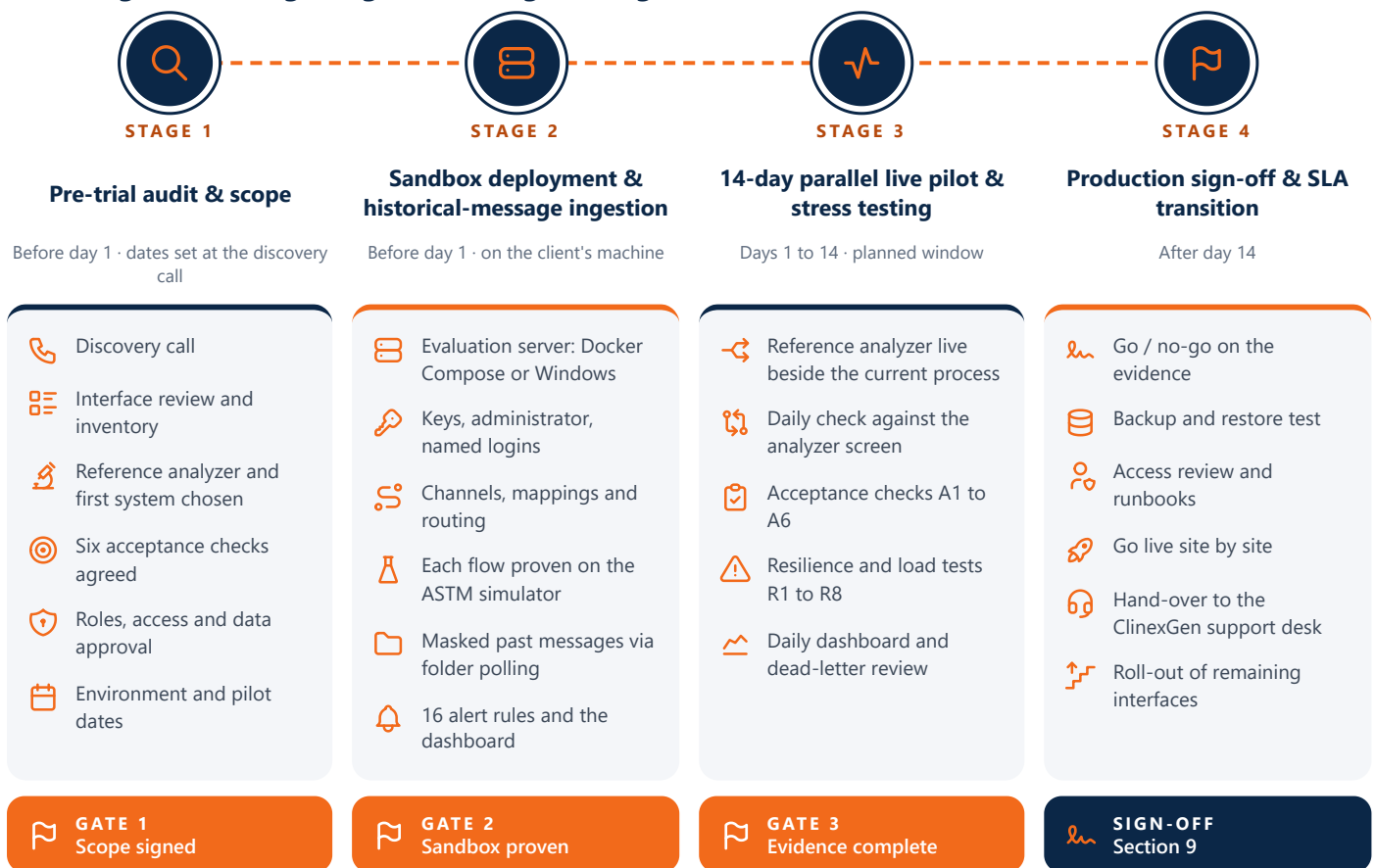
MediBridge Connect trial: four stages, from scope to sign-off

A structured proof of concept on the client's own analyzer and LIS. Both sides agree the scope, prove every flow in a sandbox, run one reference analyzer live for a planned 14 days beside the current process, and then decide go or no-go together on the evidence. The trial shows that results reach the right record without anyone re-typing them, and that faults are flagged and recovered, not silently lost.

Interfaces in the trial	Live pilot	Evidence	Decision
1 reference analyzer (ASTM) and the first system it reports to, usually the LIS	14 days planned, beside the current process; dates fixed after the interface review	32 checkpoints, 6 acceptance checks, 8 resilience and load tests, a daily log	Go, conditional go or no-go, signed by the client and ClinexGen

THE TRIAL ON ONE PAGE

Four stages, three signed gates, then go / no-go



Part A · The trial plan

For the client's trial owner and the ClinexGen trial lead. Pages 3 to 8.

- | | |
|-----------------------------|-------------------------------|
| 1 Purpose and scope | 2 Before day 1: prerequisites |
| 3 Roles and RACI | 4 The plan, day by day |
| 5 Test scenarios | 6 Data handling and privacy |
| 7 Success and exit criteria | 8 Issues and escalation |
| 9 Go / no-go and sign-off | |

Part B · Functional walkthrough

For the people running each step. Pages 9 to 14.

- | | |
|--------------|--|
| B1-B4 | Step cards for the four stages, with gates |
| B5 | Test record: A1 to A6, R1 to R8 |
| B6 | Troubleshooting |
| B7 | 14-day pilot log |
| B8 | Issue log |

01 Purpose and scope

What the trial proves, on which interfaces, for how long, and what it leaves out.

MediBridge Connect is the integration layer between clinical systems: a server that receives, checks, converts and routes clinical messages, with an operator console to set it up and watch it run. MediBridge Connect is scoped by the interfaces the client switches on, so the trial starts with one reference analyzer and the first system it reports to, and adds the rest after sign-off.

WHAT THE TRIAL PROVES

-  Results reach the right record in the LIS without anyone re-typing them, with value, unit, flags and measured time matching the analyzer screen.
-  The analyzer's host query is answered with the right tests, and orders download to the analyzer.
-  Every message is stored before it is processed, can be found and traced, and can be reprocessed. Repeats are dropped; undeliverable messages wait for review, not lost.
-  Outages are recovered: results kept while the LIS is down, an encrypted spool while the database is down, line status reported when a cable is pulled.
-  The team is alerted when a line, a system or a queue needs attention.
-  The client's own team can run it: named logins and roles, backup with a restore test, runbooks.

IN SCOPE

- ✓ One reference analyzer over ASTM E1381 / E1394 (TCP/IP or RS-232)
- ✓ The first system it reports to, usually the LIS: results, QC, host query, line status, order download
- ✓ One evaluation server on the client's machine or cloud account
- ✓ A masked sample of past messages, approved in writing
- ✓ 14 live days beside the current process

OUT OF SCOPE

- ✗ Other interfaces in the inventory: they follow in the roll-out (4.9)
- ✗ Releasing reports from pilot results: the current process stays in use until go-live
- ✗ Moving records out of a legacy database: a separate ClinexGen migration service, where needed
- ✗ Several servers sharing the load (Kubernetes, Helm): scoped for production if needed
- ✗ What an LIS such as MediBridge LabCore does after results arrive: that LIS's own trial

02 Before day 1: prerequisites

Everything ticked before the first live day. The client and ClinexGen each own a list.

The client provides

- ☐ A named trial owner, and a sponsor who signs the go / no-go
- ☐ Named lab and IT users: bench staff on the reference analyzer; IT staff for the server, network and LIS
- ☐ The reference analyzer, its host-interface settings, and a network port or serial line to the pilot server
- ☐ HIS / LIS access: LIS endpoints for results, QC, host query and line status, and the LIS team or vendor
- ☐ A machine on its network or cloud account for the evaluation server; console devices for named users
- ☐ A masked sample of past messages, approved in writing (section 6)

ClinexGen provides

- ☐ A named trial lead and delivery engineer
- ☐ The evaluation server installed: Docker Compose on one server, or the guided Windows set-up
- ☐ Console and APIs served over HTTPS (TLS 1.2 / 1.3); optional TLS on MLLP channels
- ☐ Accounts: first administrator, named logins with roles, two-factor sign-in, a scoped API key for the LIS
- ☐ Configured channels, mappings and routing, proven on the built-in ASTM analyzer simulator
- ☐ The 16 ready alert rules, the Grafana dashboard, and this plan's record sheets

INTERFACE INVENTORY · FILLED IN AT THE INTERFACE REVIEW (1.2)

SYSTEM OR ANALYZER	STANDARD	TRANSPORT	DIRECTION	MESSAGES IT SENDS	OWNER	PILOT
Reference analyzer	ASTM E1381 / E1394	TCP/IP or RS-232	Both	Results, QC, host query; receives orders	Lab	☐
						☐
						☐
						☐
						☐
						☐
						☐

Standards MediBridge Connect configures: ASTM E1381 / E1394 · HL7 v2.3 to 2.5.1 over MLLP · FHIR R4, two-way with HL7 v2 · DICOM storage · MQTT · files, email, HTTP and WebSocket.

03 Roles and RACI

Who does what. Each row has one Accountable person.


Client sponsor
 Lab director, CIO or IT head. Approves data use; signs the go / no-go.


Client trial owner
 Runs the trial day to day for the client; signs each gate.


Lab and IT users
 Bench staff on the reference analyzer; IT staff for server, network and LIS.


ClinexGen trial lead
 Plans and runs the trial with the trial owner; keeps the issue log.


ClinexGen delivery engineer
 Installs, configures channels, runs the simulator and resilience tests.


ClinexGen support desk
 One support desk and escalation path after go-live.

ACTIVITY	SPONSOR	TRIAL OWNER	LAB / IT USERS	TRIAL LEAD	DELIVERY ENGINEER	SUPPORT DESK
Discovery call and interface review	I	A	C	R	C	
Scope, success criteria and pilot dates (Gate 1)	C	A	C	R	C	
Written approval of data use (section 6)	A	R	I	C	I	
Evaluation server, keys and named logins		A	C	C	R	
Channels, mappings, routing; simulator proofs		C	C	A	R	
Masked-sample ingestion and dead letters (Gate 2)		A	C	R	R	
Daily check against the analyzer screen		A	R	I	C	
Daily dashboard, alert and dead-letter review		I	R	A	R	
Acceptance checks A1 to A6		A	R	R	C	
Resilience and load tests R1 to R8		A	C	R	R	
Issue log and escalation (section 8)	I	C	C	A	R	
Go / no-go decision and sign-off	A	R	I	R	I	I
Backup, restore test and access review		A	R	C	C	
Runbooks and hand-over to support		A	C	R	C	R
Go-live site by site and roll-out plan	I	A	C	R	R	C

R Responsible: does the work
 A Accountable: one per row, signs it off
 C Consulted before
 I Informed after

WHO SIGNS WHAT

Gate 1 Trial owner · Trial lead	Gate 2 Trial owner · Trial lead	Gate 3 Trial owner · Trial lead	Go / no-go Sponsor · Trial owner · ClinexGen
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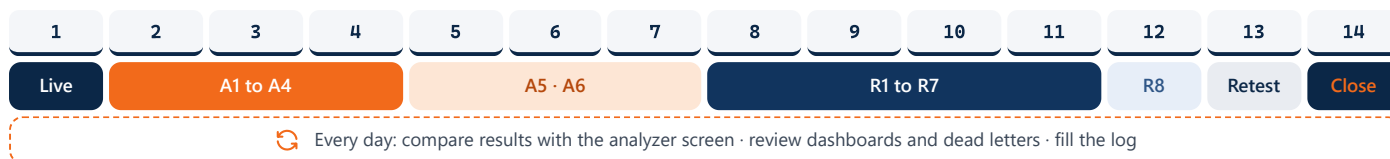
NAMED PEOPLE FOR THIS TRIAL · FILLED IN AT 1.1

ROLE	NAME	PHONE	EMAIL
Client sponsor			
Client trial owner			
Lab users (reference analyzer)			
IT users (server, network, LIS)			
ClinexGen trial lead			
ClinexGen delivery engineer			
ClinexGen support desk			

04 The plan, day by day

The four stages in order. Pilot days are planned days; dates are fixed after the interface review.

THE 14-DAY LIVE WINDOW



WHEN	WHAT HAPPENS	RESPONSIBLE	OUTPUT
1 Stage 1 · Pre-trial audit & scope before day 1			
Audit 1	Discovery call: analyzers, HIS / LIS and the interfaces needed	Trial lead, trial owner	Systems listed
Audit 2	Interface review: inventory of systems and messages; reference analyzer and first system chosen	Trial lead, IT users	Inventory complete
Audit 3	Success criteria, roles, access, written data approval, environment, pilot dates	Trial owner, trial lead	Gate 1 signed
2 Stage 2 · Sandbox deployment & historical-message ingestion before day 1			
Sandbox 1	Evaluation server installed; keys, first administrator, named logins and roles	Delivery engineer, IT users	Health checks answer
Sandbox 2	Channels, mappings and routing; each flow proven on the ASTM analyzer simulator	Delivery engineer	Results, query, orders proven
Sandbox 3	Masked past messages fed through a folder-polling channel; dead letters cleared; alerts loaded	Delivery engineer, trial lead	Gate 2 signed
3 Stage 3 · 14-day parallel live pilot & stress testing days 1 to 14			
Day 1	Reference analyzer live beside the current process; first results compared	Delivery engineer, lab users	First day logged
Days 2 to 4	Daily routine; acceptance checks A1 to A4	Lab users, trial lead	A1 to A4 recorded
Days 5 to 7	Daily routine; A5 (LIS outage) and A6 (cable pulled) in announced windows	Lab and IT users, engineer	A5, A6 recorded
Days 8 to 11	Daily routine; resilience tests R1 to R7 in announced windows	Delivery engineer, IT users	R1 to R7 recorded
Day 12	Load test R8 with the busiest day's volume	Delivery engineer	R8 recorded
Day 13	Retest anything that failed; close or grade open issues	Delivery engineer, trial lead	Issue log current
Day 14	Close the 14-day log; evidence ready for the decision	Trial owner, trial lead	Gate 3 signed
4 Stage 4 · Production sign-off & SLA transition after day 14			
Decision	Go / no-go meeting on the evidence (section 9)	Sponsor, trial owner, trial lead	Signed decision
Readiness	Backup with point-in-time recovery and a restore test; access review; runbooks; monitoring	IT users, delivery engineer	Restore test passed
Go-live	Site by site, with monitoring and alerts in place; trial data closed (section 6)	Trial owner, delivery engineer	First production day checked
Hand-over	To the ClinexGen support desk under the service levels in the proposal; roll-out plan	Trial lead, support desk	Hand-over recorded

Planned order: the trial owner and the trial lead may move a test inside the 14 days. Each announced window is agreed with the bench in advance, and the current process covers it.

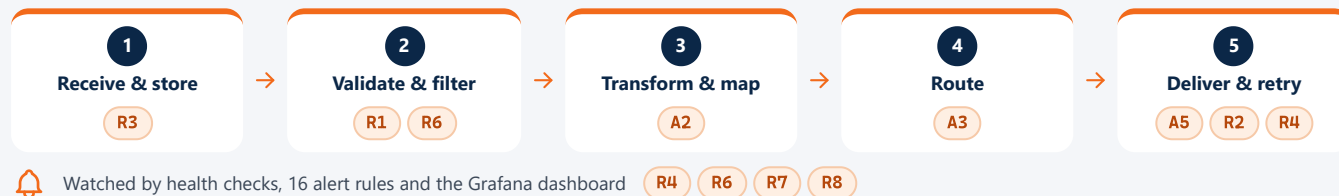
05 Test scenarios

Mapped to what MediBridge Connect is built to do. Records are kept in Part B (B5).

WHERE EACH TEST ACTS



INSIDE MEDIBRIDGE CONNECT · THE SAME FIVE STEPS ON EVERY CHANNEL



ID	SCENARIO	EXPECTED RESULT	PASS CRITERION
ACCEPTANCE CHECKS WITH THE REFERENCE ANALYZER			
 A1	Host query answered with the right tests	The analyzer asks which tests to run; MediBridge Connect asks the LIS and answers, without waiting for other deliveries	Every tube in the check runs exactly the tests ordered in the LIS
 A2	Results match the analyzer screen	Each result reaches the LIS with sample barcode, value, unit, flags, measured time and status	Every compared result matches on value, unit, flags and time
 A3	Repeat runs kept, QC routed separately	A rerun is kept as its own result; QC results go to the separate QC endpoint	Every rerun present; no QC result on a patient record
 A4	Order download listed on the analyzer	The LIS pushes the order over the running line, retried while the line is busy	Every order sent is listed on the analyzer
 A5	LIS outage: results arrive after recovery	Results are kept while the LIS is down and redelivered until the LIS accepts them	After recovery the LIS count equals the analyzer's: none missing, none doubled
 A6	Cable pulled: line status reported, flow resumes	The LIS is told the line is closed or silent, then connected again	Status shown both ways; results flow again after reconnection
RESILIENCE AND LOAD TESTS, IN ANNOUNCED WINDOWS			
 R1	Repeat message sent again	Recognised as a repeat and dropped	Delivered exactly once
 R2	Message the destination refuses	Retried, then parked in the dead-letter queue with its reason; reprocessed from the console after the fix	Delivered once after reprocessing
 R3	Database stopped briefly	Results received meanwhile go to the encrypted local spool and are replayed in arrival order	All results present, in arrival order; spool empty
 R4	One destination held	Queue depth rises and the backlog alert fires; each destination retries on its own	Alert fires and clears; backlog drains; the LIS keeps receiving
 R5	Host query during R4's backlog	Answered without waiting for the held deliveries	Every host query in the window answered
 R6	Malformed messages mixed with good ones	Malformed ones rejected by the validation profile with a reason; the error-rate alert fires	Every good message delivered; every bad one has a reason
 R7	Server stopped and restarted	The server-down alert fires; health checks fail, then pass after restart	Alert seen by the named person; channels resume
 R8	Load: the busiest day's volume	The batch drains through the folder-polling channel; processing visible on the dashboard	Every message delivered or rejected with a reason; figures recorded

R8 sets no throughput target in advance: the processing time and queue depth seen on the client's own server are recorded as the client's figures. The volume is agreed at 1.4.

06 Data handling and privacy

Under India's Digital Personal Data Protection Act, 2023 (DPDP Act).

HOW TRIAL DATA IS HANDLED



The client is the data fiduciary.

ClinexGen processes trial data on the client's behalf, only for the trial.



Real personal data only with written approval.

Stage 2 uses a masked sample of past messages; live results enter in stage 3, on the client's own server. Both are approved in writing at 1.6, and live use is confirmed again at Gate 2.



Named trial users only.

No shared logins. Viewing patient data in the console needs a separate permission, given only to the people named at 1.6.



After the go / no-go, one of two things.

Trial data is deleted, with ClinexGen confirming the deletion in writing, or carried into go-live if the client signs for it (4.8).

CONTROLS BUILT INTO MEDIBRIDGE CONNECT



AES-256-GCM field-level encryption of patient data at rest, with key rotation



TLS 1.2 / 1.3 with HSTS in transit; optional TLS on MLLP channels



Password policy, optional TOTP two-factor sign-in, lockout after repeated failures



21 permissions and 6 built-in roles; every API call denied unless permitted



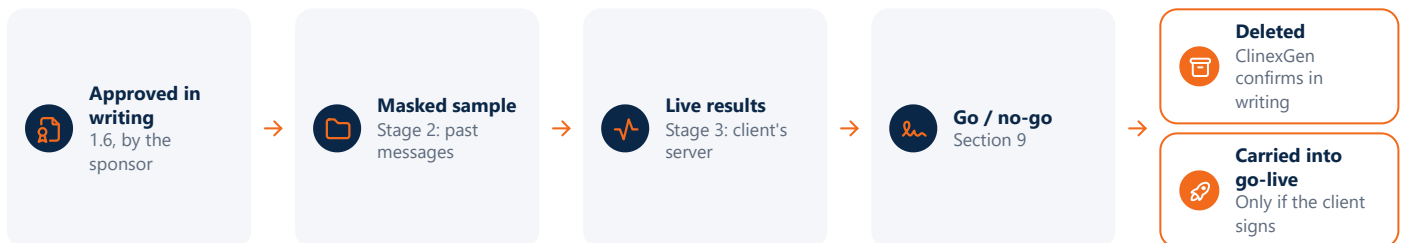
Audit trail of patient-data reads, administrative actions and API-key calls



Patient data redacted from logs; retention rules; export and erase on request

We claim no certification or independent audit; compliance also depends on how MediBridge Connect is deployed and run.

TRIAL DATA, START TO FINISH



07 Success and exit criteria

Every criterion met declares the trial successful. The client's own figures, never a quoted target.

#	CRITERION	MEASURE	MET?
1	Coverage	Every Part B checkpoint marked; every Skip has a reason	☐ Yes ☐ No
2	Acceptance	A1 to A6 all Pass, witnessed and signed (B5)	☐ Yes ☐ No
3	Results accuracy	Every result compared in the 14 days matches the analyzer screen, or its difference is closed	☐ Yes ☐ No
4	No re-typing	No pilot result needed hand entry to reach the LIS	☐ Yes ☐ No
5	Every message accounted for	Delivered, rejected with a reason, or reprocessed; none unexplained	☐ Yes ☐ No
6	Resilience	R1 to R7 all Pass (B5)	☐ Yes ☐ No
7	Load	R8 Pass; processing time and queue depth recorded	☐ Yes ☐ No
8	Alerts	Every alert that fired was seen and handled by a named person	☐ Yes ☐ No
9	Open issues	No open severity 1 or 2 issue; any severity 3 item named with an owner and a date	☐ Yes ☐ No

EXIT AND EXTENSION

The trial ends on day 14, with the go / no-go meeting (section 9).

It stops early if a severity 1 issue cannot be fixed and retested in the window, or the client withdraws its data approval. The current process carries on throughout.

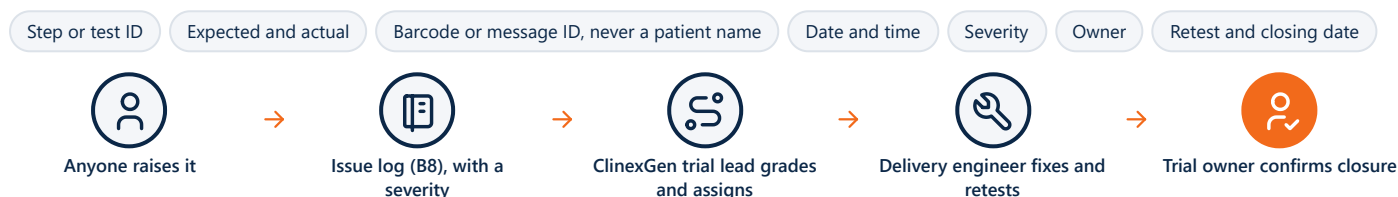
It is extended only by new dates agreed in writing by the trial owner and the trial lead, for example when the analyzer is out of service.

08 Issues and escalation

Every Fail and Blocked goes on the issue log (B8) with a severity.

SEVERITY	WHAT IT MEANS	HANDLED BY	PILOT IMPACT
1 - Critical	A result reaches the wrong record, or with a wrong value, unit or flag; or the pilot flow stops	Trial lead with the delivery engineer; trial owner and sponsor told	Pilot use of that flow pauses; the current process carries on; retest before restart
2 - Major	An acceptance check or resilience test fails; an alert does not fire; a dead letter has no clear cause	Delivery engineer; trial lead owns it; trial owner told	Fixed and retested before the go / no-go
3 - Minor	A mapping, display or report point with a workaround	Delivery engineer; on the issue log	Fixed in the pilot, or a conditional-go item with owner and date
4 - Request	A change outside the agreed scope, such as a new interface	Trial lead	Goes to the roll-out plan (4.9), not the pilot

WHAT EVERY ISSUE LINE RECORDS



 Severity 1 or 2 still open: the sponsor and the ClinexGen trial lead decide to pause, extend or continue. No response times are set for the trial. After go-live, the ClinexGen support desk works to the service levels written into the client's proposal.

09 Go / no-go and sign-off

Taken on the evidence in Part B, at the end of the 14 days.

THE EVIDENCE ON THE TABLE

 Gates 1 to 3 signed
 B5 test record
 B7 14-day log
 B8 issue log, graded
 Section 7 criteria marked

☒ **Go**
Every success criterion in section 7 is met. Stage 4 continues to go-live.

☐ **Conditional go**
Go-live goes ahead with named open items, each with an owner and a date.

☐ **No-go**
Reasons recorded; the affected stage is fixed and re-run, or the trial closes.

CONDITIONAL-GO ITEMS

#	OPEN ITEM	OWNER	DUE DATE
1			
2			
3			
4			

TRIAL DATA AFTER THE DECISION (SECTION 6)

- ☐ Deleted; ClinexGen confirms in writing on _____
- ☐ Carried into go-live; client signs on _____

HAND-OVER TO THE CLINEXGEN SUPPORT DESK

Support desk contact _____

Escalation path _____

Service levels: as written in proposal ref. _____

Client sponsor	Client trial owner	ClinexGen trial lead	For Clinexgen Private Limited
Name _____	Name _____	Name _____	Name _____
Signature _____	Signature _____	Signature _____	Signature _____
Date _____	Date _____	Date _____	Date _____

B PART B · FUNCTIONAL WALKTHROUGH

Step cards: one checkpoint each, in stage order

Mark every card, and initial it with the date. Copy every Fail and Blocked onto the issue log (B8) with a severity (section 8). The gate at the end of a stage is signed before the next stage starts.

☐ **Pass**

MediBridge Connect did what the step expects.

☐ **Fail**

It did something else: write what you saw.

☐ **Blocked**

The step could not run: write why.

☐ **Skip**

Not run on purpose: say why.

1
B1 · STAGE 1 OF 4

Pre-trial audit & scope

Purpose Agree what will be connected, how success is judged, and who signs.

Ends with Gate 1 · Scope signed

1.1 **Trial owner** **Trial lead** Discovery call: the client describes its analyzers, HIS / LIS and the interfaces it needs.

CHECKPOINT Notes list every system named, with its owner

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

1.2 **Trial lead** **IT users** Interface review: fill in the inventory (page 3) with every system, analyzer and interface, its standard and transport, and the messages each one sends.

CHECKPOINT Every row has standard, transport, direction, messages and owner

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

1.3 **Trial owner** **Lab users** Pick the reference analyzer (TCP/IP or RS-232; server or client mode) and the first system it reports to, usually the LIS. Agree where pilot results land in the LIS.

CHECKPOINT Both marked Pilot in the inventory

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

1.4 **Trial owner** **Trial lead** Agree the success criteria (section 7): the six acceptance checks, the resilience and load tests, the daily comparison sample and the R8 volume.

CHECKPOINT Criteria accepted in writing, with a witness for each check

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

1.5 **IT users** **Delivery engineer** Agree access: pilot server, network paths to the analyzer and the LIS, named console logins, the LIS API key, and remote access for ClinexGen if the client allows it.

CHECKPOINT Access list approved; no shared logins

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

1.6 **Sponsor** **Trial owner** Approve data use in writing (section 6): the masked sample for stage 2, live results for stage 3, and the people who may view patient data.

CHECKPOINT Written approval on file

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

1.7 **Trial owner** **Trial lead** Choose the environment (Docker Compose or the guided Windows set-up) and fix the dates of the 14 live days.

CHECKPOINT Dates written into the plan (section 4)

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____


GATE 1
Scope signed

Client trial owner _____ ClinexGen trial lead _____ Date _____

2

B2 · STAGE 2 OF 4

Sandbox deployment & historical-message ingestion

Purpose Prove every flow before live traffic, on the simulator and a masked sample.

Ends with Gate 2 · Sandbox proven

- 2.1** **Delivery engineer** **IT users** Install the evaluation server on the client's machine: Docker Compose on one server (server, PostgreSQL, RabbitMQ, Prometheus and Grafana in one step), or the guided Windows set-up.

CHECKPOINT Liveness and readiness checks answer; console and APIs on HTTPS

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

- 2.2** **Delivery engineer** Generate the keys and create the first administrator; install the operator console for each named user (Windows, Android, iOS or macOS).

CHECKPOINT Administrator signs in; keys kept as the key-management runbook says

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

- 2.3** **IT users** **Delivery engineer** Create a named login per user with one of the 6 built-in roles; switch on two-factor sign-in for administrators; issue a scoped API key to the LIS.

CHECKPOINT Patient-data view only for the people approved at 1.6

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

- 2.4** **Delivery engineer** Configure a channel per pilot connection: source, filters, mappings in the visual mapper, routing rules and destinations (LIS results, QC, host query, line status).

CHECKPOINT Channels deployed and started; each shows its status

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

- 2.5** **Delivery engineer** **Lab users** Prove each flow on the built-in ASTM analyzer simulator: results, host query and order download.

CHECKPOINT Results reach the LIS with barcode, value, unit, flags, time, status

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

- 2.6** **IT users** Prepare the masked sample of past messages approved at 1.6 (for example HL7 messages saved from the current interface) and count the messages in it.

CHECKPOINT Count noted; nothing identifies a real patient

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

- 2.7** **Delivery engineer** Feed the sample through a file (folder-polling) channel, with the validation profile and mappings the pilot will use.

CHECKPOINT Delivered + rejected + repeats dropped = messages fed

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

- 2.8** **Delivery engineer** **Trial lead** Review the dead-letter queue; fix the mapping or profile; reprocess from the console. Search an agreed set of messages and trace each one end to end.

CHECKPOINT Dead-letter queue empty, or every item explained

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

- 2.9** **Delivery engineer** **IT users** Load the 16 ready Prometheus alert rules and the Grafana dashboard; name who watches them during the pilot.

CHECKPOINT Dashboard shows messaging, API, database and runtime health

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____


GATE 2
Sandbox proven; live results approved for stage 3

Client trial owner _____ ClinexGen trial lead _____ Date _____

3

B3 · STAGE 3 OF 4

14-day parallel live pilot & stress testing

Purpose Run the reference analyzer live beside the current process and collect the evidence.
Ends with Gate 3 · Evidence complete

Every live day (3.2 to 3.4)

- ☐ Agreed sample compared with the analyzer screen
- ☐ Every difference logged as an issue (B8)
- ☐ Dashboards read: received, processed, failed, dead-lettered; queue and spool depth
- ☐ Dead letters reviewed and reprocessed
- ☐ The day's line in B7 initialised

Each announced window (A5, A6, R1 to R8)

- ☐ Bench and LIS team told; the current process is covering
- ☐ Start time noted; test run as in section 5
- ☐ Systems restored; line status shows connected
- ☐ Counts compared with the analyzer
- ☐ Result and witness recorded in B5

3.1 **Delivery engineer** **IT users** Day 1: connect the reference analyzer and the first system to the pilot server. The current process carries on beside it until go-live.

CHECKPOINT Line status shows connected; first results reach the LIS

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

3.2 **Lab users** **Trial owner** Every day: compare the agreed sample of results in the LIS with the analyzer screen (value, unit, flags, measured time); fill the day's line in B7.

CHECKPOINT Every compared result matches, or the difference is logged

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

3.3 **IT users** **Delivery engineer** Every day: review the Grafana and console dashboards (messages received, processed, failed and dead-lettered; queue depth; spool depth) and any alert that fired.

CHECKPOINT Monitoring columns of the day's line filled in

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

3.4 **Delivery engineer** Every day: review the dead-letter queue; fix the cause; reprocess from the console.

CHECKPOINT Nothing left unexplained at the end of the day

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

3.5 **Lab users** **Trial lead** Run acceptance checks A1 to A6 with the reference analyzer (section 5); record each in B5.

CHECKPOINT All six recorded and signed by the witness

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

3.6 **Delivery engineer** **IT users** Run resilience and load tests R1 to R8 in announced windows, with the current process covering each; record each in B5.

CHECKPOINT All eight recorded and signed

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

3.7 **Trial owner** **Trial lead** Day 14: close the 14-day log; count the days with a difference; list open issues by severity.

CHECKPOINT Evidence pack ready for the go / no-go

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____


GATE 3
Evidence complete

Client trial owner _____ ClinexGen trial lead _____ Date _____

4

B4 · STAGE 4 OF 4

Production sign-off & SLA transition

Purpose Decide on the evidence, make production ready, and hand over to the support desk.

Ends with Sign-off · section 9

4.1 **Sponsor** **Trial owner** **Trial lead** Go / no-go meeting on the evidence: the 14-day log, A1 to A6, R1 to R8 and the issue log.

CHECKPOINT Decision signed in section 9

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

4.2 **IT users** **Delivery engineer** Set up the documented PostgreSQL backup with point-in-time recovery; restore it on a separate machine and find a pilot message there.

CHECKPOINT Restore test passed; date recorded

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

4.3 **IT users** **Trial owner** Access review: run the user access review report, remove pilot-only logins and API keys, and keep two-factor sign-in on for every administrator login.

CHECKPOINT Every login and key left has an owner and a reason

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

4.4 **Trial lead** **IT users** Hand over the runbooks: key management, incident response, access review and risk assessment.

CHECKPOINT Each runbook received, with an owner named

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

4.5 **Delivery engineer** **IT users** Set up monitoring for production: health checks, the 16 alert rules and the Grafana dashboard; name the person who watches each.

CHECKPOINT An alert raised on purpose is seen by its named watcher

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

4.6 **Trial owner** **Lab users** Go live site by site: switch the reference analyzer's flow to production use and retire the parallel process for it.

CHECKPOINT First production day checked against the analyzer screen

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

4.7 **Trial lead** **Support desk** Hand over to the ClinexGen support desk: one support desk and escalation path, under the service levels written into the client's proposal.

CHECKPOINT Contacts and escalation path recorded in section 9

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

4.8 **Trial owner** **Trial lead** Close the trial data (section 6): delete what does not carry forward, with ClinexGen confirming in writing, or sign for it to carry into go-live.

CHECKPOINT Written confirmation or signed carry-forward on file

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____

4.9 **Trial owner** **Trial lead** Plan the roll-out of the other interfaces in the inventory: each configured, proven on the simulator, then on its instrument, and switched on with monitoring.

CHECKPOINT Order and dates agreed

☐ Pass ☐ Fail ☐ Blocked ☐ Skip

Tested by _____ Date _____ Signature _____



SIGN-OFF The go / no-go decision, the trial-data choice and the support hand-over are signed in section 9 (page 8).

B5 Test record: acceptance, resilience and load

Scenarios and pass criteria are in section 5. The witness signs each line.

ID	SCENARIO	RESULT	TESTED BY	DATE	WITNESS SIGNATURE
ACCEPTANCE CHECKS WITH THE REFERENCE ANALYZER					
A1	Host query answered with the right tests	☐ Pass ☐ Fail			
A2	Results match the analyzer screen	☐ Pass ☐ Fail			
A3	Repeat runs kept, QC routed separately	☐ Pass ☐ Fail			
A4	Order download listed on the analyzer	☐ Pass ☐ Fail			
A5	LIS outage: results arrive after recovery	☐ Pass ☐ Fail			
A6	Cable pulled: line status reported, flow resumes	☐ Pass ☐ Fail			
RESILIENCE AND LOAD TESTS, IN ANNOUNCED WINDOWS					
R1	Repeat message sent again	☐ Pass ☐ Fail			
R2	Message the destination refuses	☐ Pass ☐ Fail			
R3	Database stopped briefly	☐ Pass ☐ Fail			
R4	One destination held	☐ Pass ☐ Fail			
R5	Host query during R4's backlog	☐ Pass ☐ Fail			
R6	Malformed messages mixed with good ones	☐ Pass ☐ Fail			
R7	Server stopped and restarted	☐ Pass ☐ Fail			
R8	Load: the busiest day's volume	☐ Pass ☐ Fail			

B6 Troubleshooting

Likely causes and the first thing to do. Never re-type a result by hand to make a check pass.

SYMPTOM	LIKELY CAUSE	FIRST ACTION
Line shows closed or silent	Cable, port, or the analyzer's host-interface settings	Check the cable and settings against the channel; watch line status
Host query not answered	LIS query endpoint unreachable, or the sample not ordered	Check the endpoint and the order; reload the tube
Unit or flag differs from the screen	Mapping or lookup in the visual mapper	Fix the mapping; reprocess from the console; log the difference
Message in the dead-letter queue	Destination refused it, or a mapping failed	Read the reason in the console; fix; reprocess
QC result beside patient results	QC routing rule missing	Route QC to the QC endpoint; retest A3
Order not listed on the analyzer	Line busy, or downloads not enabled on the analyzer	Let the retry run; check the analyzer's settings; retest A4
Folder channel picks nothing up	Folder path or the server's rights to it	Check the path and rights
Cannot see patient data in a message	Patient view needs a separate permission	Expected; ask the administrator only if the role needs it
Backlog alert stays on	A destination is down or refusing messages	Check that destination; watch the queue depth fall
Spool-not-draining alert	The database is still unavailable	Bring the database back; the spool replays in arrival order

B7 14-day pilot log

One line per live day. Lab users fill the comparison; IT users and the delivery engineer fill monitoring.

DAY	DATE	RESULTS COMPARED	DIFFERENCES, ISSUE NO.	DEAD LETTERS NEW / REPROCESSED	ALERTS FIRED	REVIEWED BY	TRIAL OWNER
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							

Days with a difference: _____ Open issues on day 14: _____ Trial owner signature _____

B8 Issue log

Copy every Fail and Blocked here. It travels with the evidence to the go / no-go.

#	STEP	SEVERITY	WHAT HAPPENED	OWNER	CLOSED ON
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

No external certification is claimed. Service levels after go-live are those written into the client's proposal.