$\frac{IGENE-EPR\ INTERFACE\ REQUIREMENTS:}{IG-12149-INBOUND\ ORDER\ MESSAGE\ CHANGES\ \&\ IG-11347-TIE\ VALIDATION}{RULES}$

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1. Executive Summary

The current TIE validation rules were introduced in haste to support report delivery (outbound messaging) into HIVE (EPIC). At that time, our aim was to integrate iGene with HIVE within tight project delivery dates, and consideration for further integration with other systems was not a priority. We now have a requirement to integrate iGene with other Electronic Patient Record (EPR) systems, such as HODS and PatientPass, in addition to HIVE.

This document outlines the new requirements for the iGene-EPR HL7 interface. Additional requirements to establish a workflow for emailing reports not bound for EPR systems are also described.

Objectives:

1.1. Inbound Interface for Test Orders (EPR to iGene)

- Establish a single interface to accept patient referrals from multiple EPR sources via HL7 messages.
- Convert received HL7 messages into standardised PDF referral forms and automatically attach them to the corresponding referral in iGene.
- Utilise the External Referral Numbers table to determine the originating EPR system(s).
- Enable full configuration capability by the Manchester GDL without technical intervention by Genial, to support further integrations with other EPR systems.

1.2. Outbound Interface for Report Delivery (iGene to EPR)

- Implement a single interface to transmit test results and reports back to multiple EPR sources.
- Use the Delivery Method field as a trigger mechanism to send results automatically if set to EPR.
- Ensure that results are routed correctly to the designated EPR using the External Referral Numbers field.
- HL7 messages (e.g. ORU^R01) include structured test results along with attached PDF reports.
- Enable full configuration capability by the Manchester GDL without technical intervention by Genial, to support further integrations with other EPR systems.

1.3. Email Solution for Report Delivery (non-EPR delivery)

- Support an alternative report delivery mechanism via email, in addition to EPR integration.
- When the Delivery Method field is set to Email, reports are sent as attachments to designated recipients.
- Ensure that reports reach clinicians who may not have direct EPR integration or require an additional means of access.

2. Inbound Interface for Test Orders (EPR to iGene) Overview

2.1. Supported EPR Systems

- EPIC
- HODS
- PatientPass
- Additional EPRs compliant with HL7 standards

2.2. Key Functions

- Receive patient referrals from multiple EPR systems via HL7 messaging.
- Map HL7 message segments to appropriate fields within iGene.
- Convert inbound HL7 messages into a standardised PDF referral form.
- Automatically attach the PDF referral form to a new referral in iGene.

2.3. Workflow

- The EPR transmits an HL7 message containing referral data (e.g. patient, demographics, clinical notes, test codes, EPR Order ID and EPR Source).
- The **TIE** (Trust Integration Engine) processes the HL7 message and extracts relevant data.
- The extracted data is mapped to corresponding fields within iGene and formatted into a standardised PDF referral form.
- The PDF referral form is automatically attached to the relevant referral in iGene upon accessioning from the **Holding Area**.
- The report **Delivery Method** is automatically set to **EPR** by the inbound interface feed.

2.4. Error Handling

- Errors such as invalid HL7 structure, missing mandatory fields or unrecognised EPR source are logged.
- System administrators receive notifications for manual intervention.
- Acknowledgement (ACK) messages are sent to the originating EPR for each successfully received HL7 message.

3. Outbound Interface (iGene to EPRs) Overview

3.1. Trigger Mechanism

- The report **Delivery Method** field determines the transmission method (Email or EPR).
- If the report **Delivery Method** is set to **EPR**, this serves as the trigger for outbound communication.
- The External Referral Numbers Type identifies the appropriate EPR Source.
- The External Referral Numbers Number identifies the EPR Order ID.
- The trigger mechanism must support delivery of multiple test reports per referral where applicable.

3.2. Key Functions

- Extract test result data, including PDF reports, from iGene.
- Generate HL7 messages containing structured test results.
- Transmit HL7 messages to the designated EPR system.
- Support bidirectional communication where necessary for acknowledgement of results.

3.3. Workflow

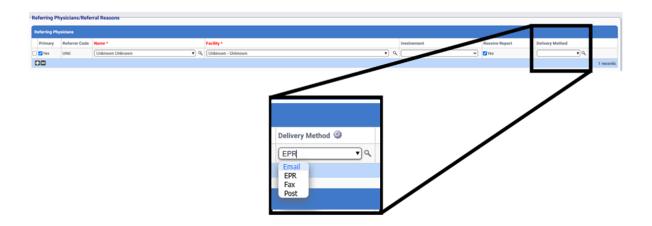
- Upon report authorisation, iGene checks the report **Delivery Method** field.
- If **Delivery Method** = **EPR**, iGene determines the destination EPR system using the **External Referral Numbers Type** for the **EPR Source**.
- The **EPR Order ID** is derived from the corresponding **External Referral Numbers Number** field.
- iGene constructs an HL7 message, including the EPR Source and EPR Order ID and any attached PDF reports.
- The HL7 message is transmitted to the designated EPR system via the TIE.
- The receiving EPR acknowledges receipt of the results message.

3.4. Error Handling

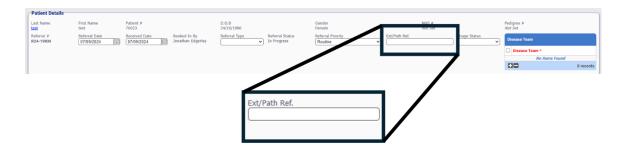
- Failed transmission, EPR system not responding or unacknowledged messages are logged for monitoring.
- Failed messages can be resent manually or automatically upon resolution.
- Retry rules can be defined as:
 - o Retry every 10 minutes for an hour, then escalate.
 - o Maximum retry limit can be configured to prevent endless looping.
- If retries fail, then a fallback action is pursued (e.g. manually emailing the report).
- Administrators are notified for troubleshooting and resolution.
- Reconciliation reports are generated to track unacknowledged messages.

4. Report Delivery Method

• The **Delivery Method** field (Path: Referral.referralInvolvments.reportDeliveryType) determines whether reports are transmitted via **Email** or **EPR**.



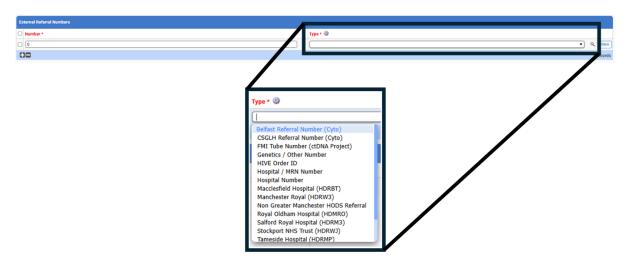
- **Delivery Method** should be set to **EPR** automatically by the inbound interface feed.
- Otherwise, the **Delivery Method** will automatically default to **Email** as determined by the preferences configuration.
- If **EPR** is set as the **Delivery Method**, this becomes the trigger for the outbound interface when the report is authorised.
- <u>PLEASE NOTE:</u> Ext/Path Ref. (Path: Referral.externalRef) will no longer be used as the outbound trigger.



• These changes relate the existing ticket **IG-11347 – TIE Validation Rules**.

5. External Referral Numbers

- The **External Referral Numbers Type** (Path: Referral.referralExternalNumbers.referralExternalNumberItem) field identifies the **EPR source**.
- The External Referral Number (Path: Referral.referralExternalNumbers.number) field identifies the EPR Order ID
- The Inbound feed automatically sets the report Delivery Method to EPR, and creates
 a new item within the External Referral Numbers table for the EPR Source and
 corresponding EPR Order ID. These identifiers are then used to trigger and direct the
 Outbound feed to TIE.
 - E.g., for HIVE referrals, the Delivery Method should be automatically set to EPR & the inbound interface creates a "HIVE" External Referral Number item ("HIVE".equals(referralExternalNumber.referralExternalNumberItem.code)) which later permits the Outbound feed to TIE as this is a HIVE referral.
- There will still be a requirement for one-way EPR integrations (Outbound interface only), or to manually establish an EPR Report Delivery for a referral.
 - E.g., for HODS EPR referrals, there will be no inbound message received, so the Delivery Method will be manually set to EPR and the External Referral Numbers item will be manually entered by Manchester GDL staff ("HODS".equals(referralExternalNumber.referralExternalNumberItem.code)) which later permit the Outbound feed to TIE as this is a HODS referral.



- It is possible that multiple EPR External Referral Numbers can be assigned to a single referral, allowing for multiple EPR Order IDs and Sources, as required.
- The EPR Order ID is stored as Number (from the inbound HL7 message).
- The **EPR Source** is stored as **Type** (from the inbound HL7 message).
- <u>PLEASE NOTE:</u> We require the ability to be able to add/change EPR Sources (External Referral Number Types) within the interface configuration ourselves, as new EPRs are integrated.

6. Data Mapping

The HL7 message that iGene receives will be used to populate the iGene fields and create the PDF. Below is an example of an inbound HL7 message that iGene may receive:

```
MSH|^~\&|EpicCare|MFT|TIE|SMHGEN|20241223111443||ORM^001|489199231|T|2.4
PID|1||20009933^^^EPI^MR||BEAKER^Luke^^^||20220816|M|||4 UNKNOWN
STREET^UNKNOWN TOWN^MANCHESTER^^M3 9WL^UNITED
KINGDOM||||||||ZPD|||||||||||F
PV1||OP|SMHRARE^^^SMH^^^^^DEPID
ORC|NW|1000130988||1001163269|||||20241223111440|GNTMD^MEDICAL
GENETICS^PHYSICIAN^^
OBR|1|1590509^EPC|1000130988|R42.1
OBR|2|1590509^EPC|1000130988|R42.2
OBR|3|1590509^EPC|1000130988|R67.1
NTE | 1 | | Comments box test | OC
PRT|1|SP||Authorizing|4708931^DESHPANDE^CHARULATA^^^^^GMCID^^^GMCID~C4708
931^DESHPANDE^CHARULATA^^^^CONS^^^CONS
PRT | 2 | SP | | Order
Entry|4708931^DESHPANDE^CHARULATA^^^^GMCID^^^GMCID~C4708931^DESHPANDE^CH
ARULATA^^^^CONS^^^CONS
OBX|1|ST|230001^Specimen 1 Type:^IGENE||Blood
OBX|13|ST|230019^High Infection risk:^IGENE||Yes
```

 The Inbound Interface should be configured to accept HL7 messages with multiple OBR segments for multiple test codes, and multiple OBX segments for multiple EPR order questions. The desired OBX field structure is as follows:

OBX | 1 | ST | EPR Question ID^EPR Question: ^IGENE | | Answer

- <u>PLEASE NOTE:</u> The full data mapping, including all OBX fields and their corresponding HIVE EPR question ID and questions, can be found in "Inbound HL7 Message Mapping v3.0" excel provided alongside this specification.
- These changes relate the existing ticket IG-12149 Inbound Order Message Changes.

7. PDF Generation

The **Genomic Testing Request Form** will serve as the template for the PDF generated from inbound HL7 messages. This form is currently used for manual test requests and will be digitally replicated to ensure continuity in existing workflows.

The generated PDF will be:

- Automatically created using a combination of data extracted from the HL7 message, and from Test Ordered and Referral fields within iGene
- **Formatted to resemble** the current paper-based form.
- Attached to the referral within iGene, allowing staff to reference it as they would with a physical request form.

Ticket: IG-12149: Inbound Order Message Changes & IG-11347 - TIE Validation Rules Customer: Manchester Genomics Diagnostic Laboratory (GDL) Specification Version: V3.0 – March 2025

Below is a screenshot of the existing PDF report template developed within iGene Test ("Tests Ordered PDF") and Jaspersoft, using existing iGene fields within the Tests Ordered area (Type: TestOrder). The amendments/support we require for this report are as follows:

- Mapping of HL7 fields within specific fields of the report
- Automatic creation and attachment of the PDF to the new referral once the referral has been accessioned from the Holding Area.

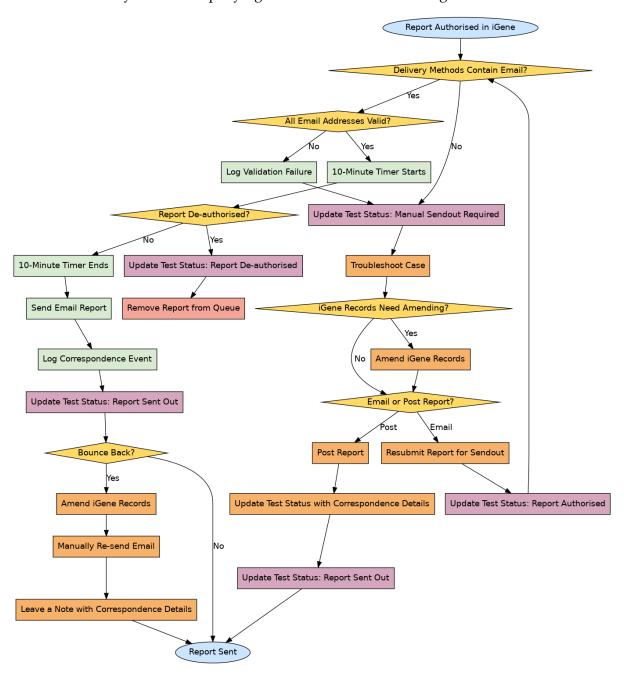
	WGLH Use Only			nic Patient Record		□ .0.
REFERR	AL CAR D		Genomic 1	Testing Request For	m	6
	SF(referralTest.referral. SF(patientName)		iource: \$F(sour	ye Header		
0.08:	SF(patient. 1964)	Order	D: \$F{orde	\$F{orderNumber}		
NHS No: \$F		Order I	Date: \$F{crea	tedAt}		
Patient Deta	ails			Referring Cli	nician/Healthcare Prof	essional
Name:	\$F{patientName}		Consu		: "PRT.5"	
D.O.B:	O.O.B: \$F{patient.dateOfBirth} Biolo		Biological Sex:		Hospital: "PRT.6"	
NHS No:	\$F	Gender:		Department:	"PRT.6"	
		Ethnicity:	"PID.22"	Email/Tel:	"PRT.7"	
Postcode:		Hospital No: "PID.3"		Cc. Report to:	*OBX.17*	
				Detail 3		
"NTE.3"		Januar	[Detail 3		I and an
Acknowledge t	hat DNA/RNA will be stor f consent for testing:	ed: "OBX.27" "OBX.19"			t relate to an ongoing pregan	cy: "OBX.24"
Acknowledge t	f consent for testing:		1		it relate to an ongoing pregan	cy: "OBX.24"
Acknowledge t Confirmation o	f consent for testing:	*OBX.19*	ample 1 Source:		t relate to an ongoing pregan Collection Date:	cy: "OBX.24"
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Acknowledge to Confirmation of Specimen D	etails *OBX.1* *OBX.6*	"OBX.19"	ample 1 Source:	Does this reques	Collection Date:	"OBX.18" "OBX.20 or OBX.21"
Acknowledge ti Confirmation o Specimen D Sample 1 Type: Sample 2 Type:	consent for testing: etails "OBX.1" "OBX.6" "OBX.8"	"OBX.19"	ample 1 Source:	Does this reques	Collection Date: NCC (%): Pathology or DNA	"OBX.18" "OBX.20 or OBX.21"
Acknowledge ti Confirmation o Specimen D Sample 1 Type: Sample 2 Type: Sample 3 Type:	consent for testing: etails "OBX.1" "OBX.6" "OBX.8"	"OBX.19"	ample 1 Source:	Does this reques	Collection Date: NCC (%): Pathology or DNA	"OBX.18" "OBX.20 or OBX.21"
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8. Email Solution for Report Delivery

iGene supports an alternative report delivery mechanism via email, in addition to EPR integration. When the report **Delivery Method** field is set to **Email**, reports are sent as attachments to designated recipients. This process ensures that reports reach clinicians who may not have direct EPR integration or require an additional means of access.

8.1. Email Report Workflow

• The email report delivery follows a structured process to ensure reliability and traceability. The accompanying flowchart illustrates this logic in detail:



<u>PLEASE NOTE:</u> Orange boxes represent manual interventions/actions by Manchester GDL staff. All other elements represent validations or actions performed by iGene.

Ticket: IG-12149: Inbound Order Message Changes & IG-11347 - TIE Validation Rules Customer: Manchester Genomics Diagnostic Laboratory (GDL) Specification Version: V3.0 – March 2025

8.2. Triggering Email Delivery

- When a test report is authorised in iGene, the system checks if the report Delivery Method for any of the recipients is set to Email.
- If this condition is met, iGene verifies the email addresses for these recipients.
- For each clinician on the referral where the report **Delivery Method** is set to **Email**, iGene checks for email addresses in clinician record at \$Person.addresses.emailAddress (this needs to be from the Clinician / facility specific record for that referral) and the \$Person.receptionistEmail.
- If an email address is present in one or both fields, the report is emailed to those email addresses.
- If one of the recipients of the report does not have an email address against them in either of the two fields, this is appended to the referral as a note and the statuses of the tests associated with the report are updated to **Manual Send Out Required**.
- If an email address(es) are present for all recipients with the report **Delivery Method** set to **Email**, a **10-minute timer** starts before sending the email.

8.3. De-authorisation Check

- If the test report is manually **de-authorised** by a Manchester GDL staff member within the **10-minute window**, the report is removed from the queue, and the send out is cancelled.
- Once the report is then **authorised** again, the report re-enters the queue with a **10-minute timer** starting again before sending the email.

8.4. Email Transmission

- After the timer expires, the report is sent as an **email attachment**.
- Once the email script has run, a correspondence event is added to the patient record

 this could be run via a post-status change script with the correspondence event
 wording determined by the Manchester GDL.

<u>PLEASE NOTE</u>: A correspondence event post-status change script has already been developed as a Custom Test Transition within Test Status Templates – but this currently requires a manual test status change trigger. We require this correspondence event process to be automated during the email workflow.

- This **correspondence event** will record the referral number linked to the report that has been sent out.
- Correspondence type set to **Email**.
- Date set to the date that the event has created.
- The test status updates to **Report Sent Out** to indicate successful transmission.

This email solution provides a structured, accountable, and traceable method for delivering reports to healthcare professionals when EPR integration is not available or feasible.