

BluPRINT Rx

Powered by TruTYPE • TruRISK • TruSELECT

A Longitudinal Medication Intelligence, Rx4Life Enrollment, and
Pharmacogenomic Management Model

PHELIX — Pharmacy. Health. Genetics.
e-PHELIX — Electronic PGx & Report Ordering

SCIENTIFIC / CLINICAL WORKFLOW WHITE PAPER

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Purpose

This paper describes a proposed end-to-end model in which medication reconciliation and pharmacokinetic risk assessment occur before PGx testing; qualifying patients can then proceed to provider-authorized PGx ordering, after which genetic results are incorporated into an updated BluPRINT Rx. Patients who do not qualify for PGx remain in the same longitudinal medication-management workflow without genetics. The paper describes intended workflow and scientific rationale, not a claim of payer coverage, regulatory clearance, or clinical validation.

Executive Summary

BluPRINT Rx is conceived as the longitudinal clinical report and patient medication-intelligence record generated within PHELIX, an electronic pharmacy, health, genetics, and medication-management platform. Rather than treating pharmacogenomic testing as the beginning of the workflow, the model begins with the patient's current medication regimen, diagnoses, reported side effects, and available clinical information.

A preliminary BluPRINT Rx uses TruTYPE to assess current pharmacokinetic context, TruRISK to prioritize established medication risks in that context, and TruSELECT to support structured evaluation of alternatives. This preliminary analysis can also identify whether the patient's medication and clinical circumstances appear to meet applicable PGx coverage criteria. The treating provider—not the software—determines and documents medical necessity and authorizes the laboratory order.

The key workflow innovation

Medication reconciliation first → identify current pharmacokinetic and medication risks → determine whether an actionable gene-drug question exists → provider reviews and documents medical necessity → e-PHELIX transmits the PGx order → genetic results are incorporated → BluPRINT Rx is regenerated → the patient remains under longitudinal medication management.

This sequence aligns conceptually with Medicare PGx coverage logic. The Novitas L39063 LCD, for example, requires a clinical need for a medication with a known actionable gene-drug interaction whose result would directly affect drug management; it also requires an appropriately qualified treating clinician who understands the actionability of the ordered test. CMS separately states that the treating practitioner must order laboratory testing and document medical necessity in the medical record [1,2].

Patients who do not meet PGx criteria are not excluded from the platform. They remain eligible for medication reconciliation, TruTYPE analysis based on available non-genetic information, TruRISK review, TruSELECT evaluation, side-effect tracking, medication-change logging, and longitudinal report generation. Genetics becomes an additional data layer when clinically appropriate—not a prerequisite for medication intelligence.

The patient-facing component, my BluPRINT Rx, provides a QR-enabled mechanism for patient-directed sharing with outside clinicians and pharmacies. The preferred architecture is a secure link rather than embedding protected health information directly in the QR code. Standards such as HL7 SMART Health Links demonstrate a model for QR-based access to evolving health data with time limits, PIN protection, and authenticated retrieval [8].

1. The Clinical Problem

Medication management is fragmented across prescribers, pharmacies, laboratories, EHRs, and time. A patient may receive medications from several clinicians, while a PGx result may be generated once and then stored as a static laboratory report. Yet the patient's medication regimen—and therefore drug-drug interactions, inhibition, induction, phenoconversion, exposure, and adverse-effect context—can change repeatedly.

FDA emphasizes that a patient's genetic makeup is only one of many factors affecting drug concentrations and response. Its pharmacogenetic association table includes multiple examples in which

genetic phenotype changes systemic concentrations, adverse-reaction risk, or dosing, while cautioning that genetics should be interpreted with other patient information [3].

The BluPRINT Rx/PHELIX model addresses this fragmentation by treating medication intelligence as a longitudinal process with PGx inserted when an actionable clinical question and medical-necessity pathway are present.

2. Platform Architecture

Component	Primary role	Clinical question
PHELIX	Longitudinal patient/provider medication-management platform	Where are the patient, medication history, reports, PGx status, side effects, and audit trail managed?
Rx4Life	Patient enrollment and longitudinal continuity program	How is the patient enrolled once, linked to providers, and kept in ongoing medication management across reports, medication changes, PGx status, doctors, and pharmacies?
e-PHELIX	Electronic ordering workflow for PGx tests and BluPRINT Rx reports	How is a provider-reviewed order generated, transmitted, tracked, and linked to results?
TruTYPE	Dynamic pharmacokinetic intelligence layer	How may the patient's current regimen and genetics, when available, affect functional drug processing?
TruRISK	Patient-specific risk stratification layer	Which established medication risks may deserve greater attention in the current PK/PD/disease context?
TruSELECT	Prospective alternative-evaluation layer	How would a contemplated medication or alternative fit the patient's current pharmacokinetic and risk profile?
BluPRINT Rx	Integrated clinician-facing report	What is the current medication intelligence picture?
my BluPRINT Rx	Patient-controlled digital access/sharing layer	How can the patient securely share a current view with another doctor or pharmacy?

3. End-to-End Clinical Workflow

3.0 Rx4Life Patient Enrollment and Longitudinal Continuity

Rx4Life is the patient enrollment and continuity layer of the BluPRINT Rx ecosystem. Enrollment creates the durable patient relationship that allows medication intelligence to persist beyond a single office visit, report, laboratory order, or prescriber. PHELIX manages the professional workflow around that enrolled patient; Rx4Life keeps the patient connected to the longitudinal medication-management program.

The Rx4Life record should preserve the patient's unique identifier, participating-provider relationships, current and historical medication regimens, reported side effects, BluPRINT Rx versions, PGx status and results when available, and the audit history of report runs and clinical changes.

A patient does not need to qualify for PGx testing to remain enrolled in Rx4Life. Non-PGx patients continue to receive medication reconciliation, TruTYPE analysis from available information, TruRISK review, TruSELECT evaluation, report versioning, side-effect tracking, and medication-change tracking. If an actionable gene-drug question arises later, PGx eligibility can be reassessed within the same record.

3.1 Patient enrollment and identity linkage

Rx4Life enrollment establishes the longitudinal patient record. Each enrolled patient is assigned or linked to a unique internal patient identifier and associated with the ordering or managing provider. The longitudinal record should maintain provider relationships without assuming that one clinician owns all subsequent medication decisions. Additional authorized clinicians or pharmacies can be associated with the patient over time.

- Core patient identifiers and demographics required for safe matching.
- Ordering/managing provider identifier and organization.
- Current medications, doses, routes, and status.
- Relevant diagnoses/clinical indications.
- Reported medication side effects or prior intolerances.
- PGx status: not ordered, pending, resulted, or unavailable.
- Versioned reports and a complete event/audit log.

3.2 Preliminary medication reconciliation and BluPRINT Rx

Before PGx ordering, PHELIX generates a preliminary medication-intelligence report. The report is valuable in its own right: it reconciles the active regimen and applies TruTYPE, TruRISK, and where relevant TruSELECT without requiring genetic data.

Preliminary report objective

Establish what is already knowable from the current regimen before ordering genetics. PGx is then targeted to an actionable unanswered question rather than used as an indiscriminate first step.

3.3 Pharmacokinetic reconciliation with TruTYPE

TruTYPE maps the medication regimen to relevant metabolic pathways and identifies clinically supported inhibition, induction, and phenoconversion effects. When PGx is not yet available, inherited function should be represented as unknown rather than presumed normal. When PGx is later added, the inherited component can be combined with current medication-related modifiers to generate an updated functional phenotype.

This is consistent with published phenoconversion literature demonstrating that genotype-predicted phenotype can differ from functional phenotype in the presence of inhibitors, inducers, and other factors [4-6].

3.4 Risk prioritization with TruRISK

TruRISK places established drug-drug, pharmacodynamic, disease-related, and adverse-effect risks into the patient's current pharmacokinetic context. The intended output is risk prioritization or mechanistic plausibility—not an unvalidated absolute probability of an adverse event.

3.5 Alternative evaluation with TruSELECT

TruSELECT can evaluate a contemplated medication or class alternative against the current regimen. Importantly, the prospective drug may itself change enzyme activity or risk relationships, so the analysis should recalculate the complete medication picture rather than evaluate the new drug in isolation.

4. PGx Medical-Necessity Support and e-PHELIX Ordering

The preliminary report can be used to identify an actionable gene-drug question and organize the information a treating provider needs to determine whether PGx testing is medically reasonable and necessary under the applicable payer policy. For Medicare under Novitas L39063, coverage requires a condition for which clinical evaluation has determined the need for a medication with a known actionable gene-drug interaction and for which the genotype result would directly affect drug management [1].

Critical compliance distinction

PHELIX can identify, organize, and draft evidence supporting medical necessity. It should not 'authorize medical necessity.' The treating provider determines medical necessity, reviews the supporting facts, edits or accepts the rationale, and signs/authorizes the PGx order. Payer coverage remains subject to the applicable policy and claim review.

4.1 Proposed PGx qualification screen

- Is the patient currently taking, or is the treating clinician considering, a medication with a clinically actionable gene-drug relationship?
- Is the gene-drug relationship supported by the payer's accepted evidence source, such as applicable FDA labeling/table or CPIC level specified by policy?
- Would the result have a plausible direct effect on selection, avoidance, dose, monitoring, or another covered drug-management action?
- Is the ordering clinician responsible for pharmacologic management of the relevant condition and qualified under applicable law and payer policy?
- Is the required diagnosis, medication indication, and clinical rationale present in the record?
- Has prior PGx testing been checked to avoid unnecessary duplicate testing?

4.2 AI-generated provider reason for PGx testing

An AI function can draft a concise provider rationale from structured order data and the preliminary BluPRINT Rx. The draft could identify the relevant medication, indication, gene-drug relationship, current pharmacokinetic concerns, and the specific management question the genetic result is intended to resolve.

Human-in-the-loop requirement

The AI-generated rationale should be labeled DRAFT, trace its supporting data, avoid inventing diagnoses or symptoms, and require provider review/edit/attestation before it becomes part of the order or medical record. The provider remains responsible for the clinical determination and documentation.

4.3 e-PHELIX order generation

Order element	Function
Patient / provider linkage	Ensures the test, result, and report return to the correct longitudinal record.
Medication + indication	Documents the drug-management context that triggered testing.
Gene/test selection	Limits ordering to the clinically relevant test or panel supported by the workflow and payer rules.
Medical-necessity rationale	Provider-reviewed documentation supporting why the result is expected to affect management.
Provider authorization	Electronic signature/attestation by the treating qualified clinician.
Laboratory routing	Secure transmission to the selected qualified laboratory.
Status tracking	Ordered → specimen pending → received → processing → resulted → incorporated into BluPRINT Rx.

5. Post-PGx: Genetics Becomes an Additional Layer

When results return, PHELIX does not replace the preliminary report with a disconnected genetic report. Instead, genetic findings are attached to the existing patient record and TruTYPE is recalculated using both inherited function and current phenoconversion modifiers.

FDA's pharmacogenetic resources provide examples in which genotype can alter systemic concentrations, adverse-event risk, response, or dose. FDA also notes that genetics is one of multiple factors affecting concentrations and response, which supports an integrated rather than genetics-only interpretation [3,7].

Before and after PGx

PRE-PGx BluPRINT Rx: medication regimen + non-genetic PK modifiers + TruRISK + TruSELECT.

POST-PGx BluPRINT Rx: the same longitudinal model + genetic information + updated functional phenotype + recalculated risk and alternative-drug context.

6. AI-Generated Post-Test Medication Action Plan

After genetic results are incorporated, an AI-assisted function can generate an editable medication action-plan draft. The plan should synthesize—not invent—the relevant PGx guideline, current medications, TruTYPE functional phenotype, TruRISK findings, and potential TruSELECT alternatives.

- Summarize actionable PGx findings in plain clinical language.
- Identify current medications directly affected by the result.
- Separate guideline-supported actions from informational findings.
- Highlight current phenoconversion that may modify genotype-only interpretation.
- Suggest issues for clinician consideration, including dose review, monitoring, or alternatives only where supported by the cited evidence.
- Allow the clinician to edit, accept, reject, or defer each proposed action.
- Record who approved the final plan, when, and which report/data version was used.

AI safety principle

AI should function as a documentation and synthesis assistant. It should not autonomously prescribe, discontinue, dose, or authorize therapy. Final medication actions remain with the appropriately licensed clinician.

7. Patients Who Do Not Qualify for PGx

A major strength of the architecture is that PGx eligibility does not determine whether a patient receives medication-management value. A patient who does not meet payer medical-necessity criteria—or for whom PGx is not clinically indicated—continues through the same PHELIX longitudinal workflow.

PGx-qualified patient	Non-PGx patient
Preliminary medication reconciliation	Same preliminary medication reconciliation
TruTYPE with non-genetic data, then genetics when resulted	TruTYPE using available non-genetic information; inherited function remains unknown
TruRISK	TruRISK
TruSELECT	TruSELECT
Medication-change log	Medication-change log
Reported side-effect log	Reported side-effect log
Versioned BluPRINT Rx reports	Versioned BluPRINT Rx reports
PGx order/result lifecycle	No PGx lifecycle unless clinical circumstances later change

This creates a medication-management platform rather than a PGx-only ordering system. If a later medication change creates an actionable gene-drug question, the patient can be reassessed for testing without creating a new disconnected record.

8. Longitudinal Report Repository and Clinical Audit Trail

Every BluPRINT Rx run should be versioned. The platform's clinical value depends not only on the current report but on the ability to reconstruct how the patient's regimen and risk profile changed over time.

Logged event	Examples of captured data
Report run	Date/time, requesting user, algorithm/knowledge-base version, medication snapshot, PGx status.
Medication change	Added, discontinued, dose/route changed, prescriber/source when known.
Side effect	Patient- or provider-reported symptom, onset, severity, suspected medication, status.
PGx event	Order, specimen, result, result amendment, gene/phenotype interpretation.
Provider action	Reviewed, plan edited, medication action accepted/rejected/deferred.
External access	Who accessed my BluPRINT Rx, access type, time, expiration/revocation when applicable.

9. my BluPRINT Rx: Patient-Directed Sharing

my BluPRINT Rx is the patient-facing digital access and sharing capability associated with Rx4Life enrollment. A QR code can allow the enrolled patient to share a secure, view-only version of the current BluPRINT Rx with another physician or pharmacy. The recipient can review the authorized information and may choose to enroll as a participating PHELIX provider or pharmacy, subject to credentialing, authorization, and the patient's permissions.

HL7 SMART Health Links provide a useful standards model: a QR can point to evolving FHIR data rather than contain the clinical data itself, and the link can support expiration, limited use, PIN protection, and authenticated retrieval. The standard explicitly contemplates a patient presenting a QR to give a specialist access to health data [8].

Recommended QR architecture

QR → secure opaque link/token → authentication and/or patient-approved access → view-only current BluPRINT Rx. Avoid placing medication lists, genetic results, or other PHI directly in the visible QR payload. Support expiration, revocation, audit logging, and least-privilege access.

FHIR-based APIs are now foundational to U.S. health information exchange and patient access. ONC describes FHIR as a widely used standard incorporated into federal health-IT certification for electronic health-information access and exchange [9]. A FHIR-oriented architecture would improve future EHR, laboratory, pharmacy, and patient-app integration.

10. Data Model: One Patient, Many Clinical Moments

Longitudinal object	Purpose
Patient master record	Stable identity anchor and consent/access settings.
Provider relationships	Ordering provider plus later participating clinicians/pharmacies.
Medication timeline	Current and historical regimen with effective dates.
Clinical context	Diagnoses, indications, organ-function data when available, reported side effects.
PGx profile	Genotype, diplotype/phenotype, laboratory source, date, interpretation version.
TruTYPE state	Versioned functional PK map at each report time.
TruRISK state	Versioned risk-priority output and supporting evidence.
TruSELECT scenarios	Alternative-drug analyses preserved as scenarios, not necessarily prescriptions.
BluPRINT Rx reports	Immutable report snapshots plus a clearly identified current report.
Audit/event log	Complete chronology of data changes, access, orders, reports, and approvals.

11. Scientific Rationale for the Integrated Model

The integrated architecture rests on several established principles. First, genetic variants can alter drug metabolism and exposure [3,7]. Second, concomitant medications can alter functional phenotype through inhibition, induction, and phenoconversion [4-6]. Third, drug-drug-gene interactions can alter the severity or clinical relevance of medication interactions [10]. Fourth, a patient's regimen changes over time, so a one-time genotype result benefits from reinterpretation in the context of the current medication environment.

The novel product proposition is the workflow integration: pre-test pharmacokinetic reconciliation, targeted PGx medical-necessity support, electronic ordering, post-test reinterpretation, longitudinal report management, patient-directed sharing, and AI-assisted provider documentation within one patient-centered record.

12. Compliance and Clinical Governance

- Medical necessity: software may support evidence gathering and drafting; the treating provider determines and documents medical necessity.

- Ordering authority: PGx orders require the appropriately qualified treating clinician under applicable payer policy and state law.
- Coverage: a positive platform screen does not guarantee payer payment; payer-specific policies, prior authorization, coding, and benefit rules remain controlling.
- AI provenance: every generated rationale/action plan should show the data and evidence used, the model/version, and provider approval status.
- Clinical evidence: gene-drug and DDI rules should be version-controlled and traceable to FDA labeling, FDA association tables, CPIC/DPWG or other approved sources as applicable.
- Privacy/security: role-based access, encryption, authentication, audit logs, consent management, minimum-necessary access, breach controls, and HIPAA/security review are essential.
- Genetic information: apply heightened access controls and applicable federal/state protections; avoid unnecessary exposure of genetic details in shared views.
- Interoperability: favor standards-based APIs and structured medication, condition, laboratory, and genomic data where practical.
- Change management: every report should record the knowledge-base and algorithm version so historical outputs remain reproducible.

13. Proposed Clinical Validation Program

Phase 1 — Workflow and analytical verification

Confirm identity matching, medication reconciliation, pathway mapping, PGx qualification rules, order completeness, report versioning, and deterministic recalculation.

Phase 2 — Medical-necessity concordance

Compare the platform's PGx qualification flags and AI-drafted rationale with independent expert review under specific payer policies. Measure false-positive and false-negative qualification rates.

Phase 3 — Pharmacokinetic/PGx concordance

Compare TruTYPE functional phenotypes and post-PGx interpretation with expert pharmacogenomic review and, where available, measured drug concentrations or validated metabolic phenotypes.

Phase 4 — Clinical utility

Measure medication-reconciliation time, actionable issue detection, provider acceptance of AI drafts, changes in medication management, and downstream adverse-event or utilization outcomes.

Phase 5 — Network/interoperability utility

Evaluate whether my BluPRINT Rx improves medication-list continuity and availability of PGx information across independent clinicians and pharmacies.

14. Example Patient Journey

1. Patient is enrolled in Rx4Life and linked within PHELIX to the treating provider and a unique patient ID.
2. Current medications, diagnoses, and reported side effects are reconciled.
3. A preliminary BluPRINT Rx is generated using TruTYPE, TruRISK, and TruSELECT without assuming genetic function.

4. The platform identifies an actionable medication/gene question and presents payer-policy criteria to the provider.
5. AI drafts a provider reason for testing from the structured clinical facts and preliminary report.
6. Provider reviews/edits the rationale, confirms medical necessity, selects the appropriate test, and authorizes the e-PHELIX order.
7. Order and specimen status are tracked until the laboratory result returns.
8. PGx data are attached to the same patient record; TruTYPE is recalculated with genetics plus current phenoconversion.
9. A full genetics-enabled BluPRINT Rx is generated and stored as a new immutable report version.
10. AI drafts an editable post-test medication action plan; the provider decides what, if anything, to implement.
11. Medication changes and reported side effects are logged, causing future reports to reflect the new regimen.
12. The patient can share a current view through my BluPRINT Rx with another doctor or pharmacy; participating professionals can enroll for ongoing authorized access.

15. Strategic Clinical Positioning

BluPRINT Rx is not simply a PGx report.

It is a longitudinal medication-intelligence record that can begin before genetics, determine whether genetics may add actionable value, incorporate PGx when medically appropriate, and continue to update as medications and patient circumstances change.

This distinction expands the clinical model beyond the relatively small moment when a genetic test is ordered. Every patient can enter through medication reconciliation. Some patients proceed to PGx. All patients can remain in ongoing medication management.

One-platform concept

PHELIX manages the patient and workflow.

e-PHELIX manages electronic orders.

TruTYPE maps current pharmacokinetic function.

TruRISK prioritizes personalized medication risk.

TruSELECT evaluates prospective alternatives.

BluPRINT Rx communicates the integrated clinical picture.

my BluPRINT Rx lets the patient securely carry and share that picture across the care network.

16. Conclusion

The BluPRINT Rx/PHELIX/Rx4Life model reorganizes PGx around medication management rather than organizing medication management around a genetic test. The workflow begins with what the clinician

must already understand—the patient's current medications, indications, risks, and side effects. Pharmacokinetic reconciliation can then reveal whether a clinically actionable genetic question exists.

When PGx is justified and ordered by the treating provider, genetics becomes a durable new data layer inside the same longitudinal record. When PGx is not justified, the patient remains enrolled in Rx4Life and continues to receive ongoing medication reconciliation and risk management. This creates a scalable clinical architecture in which genetics is targeted, medication intelligence is continuous, and the patient's current BluPRINT Rx can follow the patient across prescribers and pharmacies.

The scientific components are supported by established PGx, phenoconversion, drug-interaction, and interoperability literature. The integrated workflow, proprietary algorithms, AI functions, and claimed clinical benefits require their own validation, governance, privacy/security review, and payer-specific compliance testing before broad clinical deployment.

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Important Evidence and Regulatory Note

The references support individual scientific, coverage, documentation, and interoperability principles. They do not independently validate BluPRINT Rx, PHELIX, e-PHELIX, TruTYPE, TruRISK, TruSELECT, the proposed AI functions, or the integrated workflow. Coverage policies differ by payer and jurisdiction and can change. The final implemented product should undergo formal legal, privacy, security, clinical, laboratory-ordering, payer-policy, and regulatory review before deployment. Patent status and scope should be stated only in accordance with the actual issued/pending intellectual-property record.