| Health Technology Review | |
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| **Technology Ref.:** | HTA-24016 |
| **Technology Name/Version/Model:** | M42 Biogenix Pharmacogenomics report powered by PharmCAT |
| **Approvals by International Bodies:** | The drugs list in PharmCAT is FDA approved |
| **Company name:** | M42 |
| **Agent in UAE:** | M42 |
| **Email:** | akoshy@m42.ae |

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| **Short Description of the Technology:** | M42's Pharmacogenomics Services offer a streamlined approach, which detects individual's genetic makeup that indicates the way the person will metabolize a drug. M42 performs both the sequencing of human DNA and the generation of a detailed report. This report is entirely automated by our robust reporting engine. This engine utilizes a suite of tools for analysing genetic data, including, identification of person specific genetic variations (genotype calling), linking these variations to potential traits (phenotype creation), and chromosomal phasing. The entire process is meticulously documented and auditable, ensuring transparency and trust. Additionally, our platform is highly scalable to accommodate increasing demands, all while maintaining a rigorous 7-level Quality Control process throughout the pipeline<br>The primary objective of the M42 Pharmacogenomics report (the "Report") is to facilitate the implementation of personalized treatment Recommendations based on an individual's unique genetic composition (genotype) and its impact on drug metabolism. Research has found that people fall in one of four general metabolizers types, such as Normal, Intermediate, Poor, or Rapid/Ultrarapid, depending on their metabolic rates. The Report provides analysis of 23 patient's genes and determines individual rate of metabolism for each of 128 drugs for the patient.<br>This user-friendly Report comprises of four sections: Actionable Insights, providing swift decisions for Poor, Intermediate, and Rapid Metabolizers along with dosage recommendations; Detailed Guidelines, offering comprehensive recommendations and implications; a gene summary panel; and citations. The Report is powered by PharmCAT, an open source clinical annotation tool for phenotype generation. PharmCAT incorporates guidelines from the Clinical Pharmacogenetics Implementation Consortium (CPIC). The Report's recommendations adhere to CPIC and DPWG guidelines for a customized approach to patient care. Physicians can conveniently access these reports through the Malaffi portal. The Report is intended to act as a decision support tool with the aim of reducing errors in prescribing medications.<br>Healthcare organizations and academic medical centers are actively |

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| | implementing genomic medicine, focusing on developing a software tool in collaboration between the Pharmacogenomics Knowledgebase (PharmGKB) and the former PGRN Statistical Analysis Resource. This tool extracts guideline variants from genetic datasets (in vcf format), interprets variant alleles, and generates a report with genotype-based prescribing recommendations for informed treatment decisions.<br>This is not a replacement for therapeutic drug or clinical monitoring, but rather a decision support tool aimed at reducing "trial and error" approach for prescribing of optimal medications. |

| **Health Technology Assessment Team Recommendation:** | **Approved with limitation** |
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**Summary of Review:**

Pharmacogenomics offers valuable insights at a population level, helping researchers, healthcare professionals, and policymakers understand genetic variations in drug responses. This knowledge tailor's treatments, improves outcomes, and informs public health measures, reducing disparities. The system is not only making the insights intuitive, but also seamlessly integrates into the workflow making it easy for physicians to take data driven decisions. The Report aims to provide better personalized medication recommendations to reduce incorrect dosage and adverse events.

| Advantages | Disadvantages |
|---|---|
| Provide healthcare professionals via Malaffi Portal have the ability to access the store reports containing critical information related to patient health, medication management, and treatment outcomes. | It has to ensure the information security in place |
| Implement encryption and secure storage mechanisms to safeguard sensitive reports in a protected environmen | It depends on the interaction between gene and drugs but not between drugs-to-drugs reactions. |
| The Report is intended to highlight such risks Genetic risk for adverse drug reactions (ADRs) , thus assisting providers with selecting of appropriate medications. The aim is therefore to enhance patient safety. | |
| The TAT for sending a single PGx report shall be 48-72 hrs. This includes getting reports, checking their quality, sequencing samples, and running the PGx process. | |
| Authorized Users who can use the Malaffi System can get reports in PDF format. | |

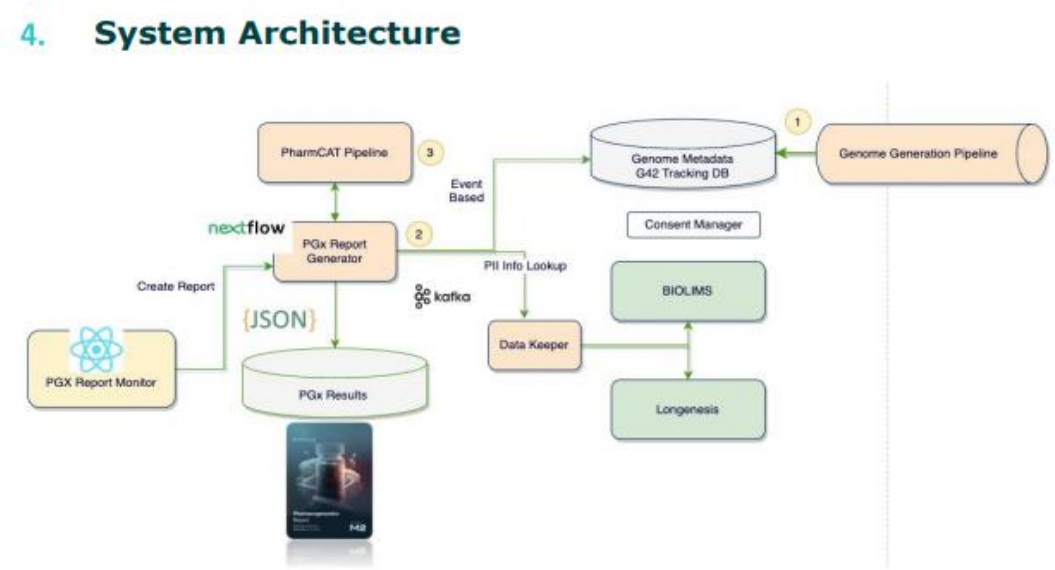
We recommend an **approval with limitation** for Market entry with the following conditions:

1. For the technology: PharmCAT (v2.5.0).
2. The technology should be performed by trusted and well-established Healthcare Facilities.
3. Compliance with all DOH information security requirements.
4. Alternate option for authentication and monitoring is enabled instead of 'break the seal'

5. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
6. Provision of regular updates and reports about the product to DOH upon request.

**Moreover,** DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

**Technology Image**




## Population, setting and intended user for Technology "PharmCAT"

- **Population/ Intended User**;
  - The Report provides analysis of 23 patient's genes and determines individual rate of metabolism for each of 128 drugs for the patient.
- **To be performed by**:
  - Healthcare providers
- **Clinical Setting:**
  - Hospitalis and clinics
- **Condition of use:**
  - Patients undergoing long-term medication.
  - Individuals with chronic ailments.
  - Patients prone to side effects or adverse reactions.
- **Exclusion criteria:**
  - NA