



# Progress and challenges in personalized medicine implementation

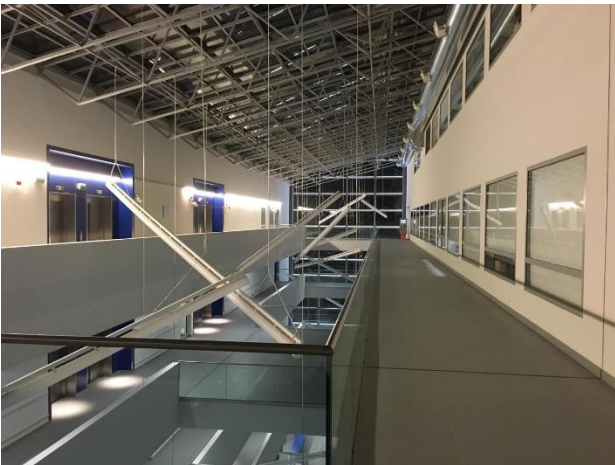
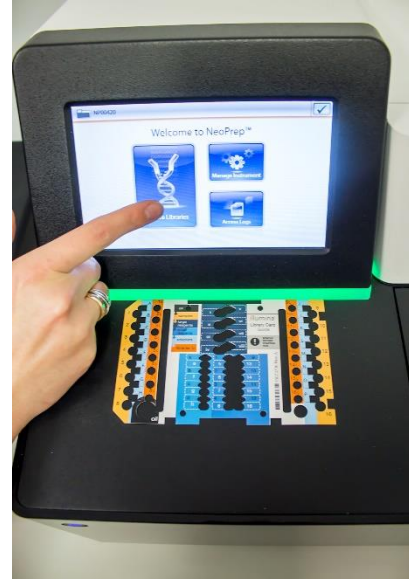
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Medical University of Białystok

# MEDICAL UNIVERSITY OF BIALYSTOK



## CENTRE FOR CLINICAL RESEARCH





# CENTRE FOR BIOINFORMATICS AND DATA ANALYSIS



## Precision medicine limitations:

- ✓ Problems with SOPs and with the implementation of SOPs
  - biobanking
  - data integration
  - data analysis
  - data storage and safety
  - data interpretation
  - decision-making proces
  - reporting
- ✓ Narrow pool of effective prognostic and diagnostic markers
- ✓ Limited number of effective drugs
- ✓ Simplified solutions for patient's data interpretation
- **decisions inadequate or not as personalized as expected**

# MOBIT Project: Molecular Biomarkers for Individualized Therapy

- Project funded by The National Centre of Research and Development within R&D Strategmed Programme „Prevention practices and treatment of civilization diseases”. Project budget: 4 362 335 EUR



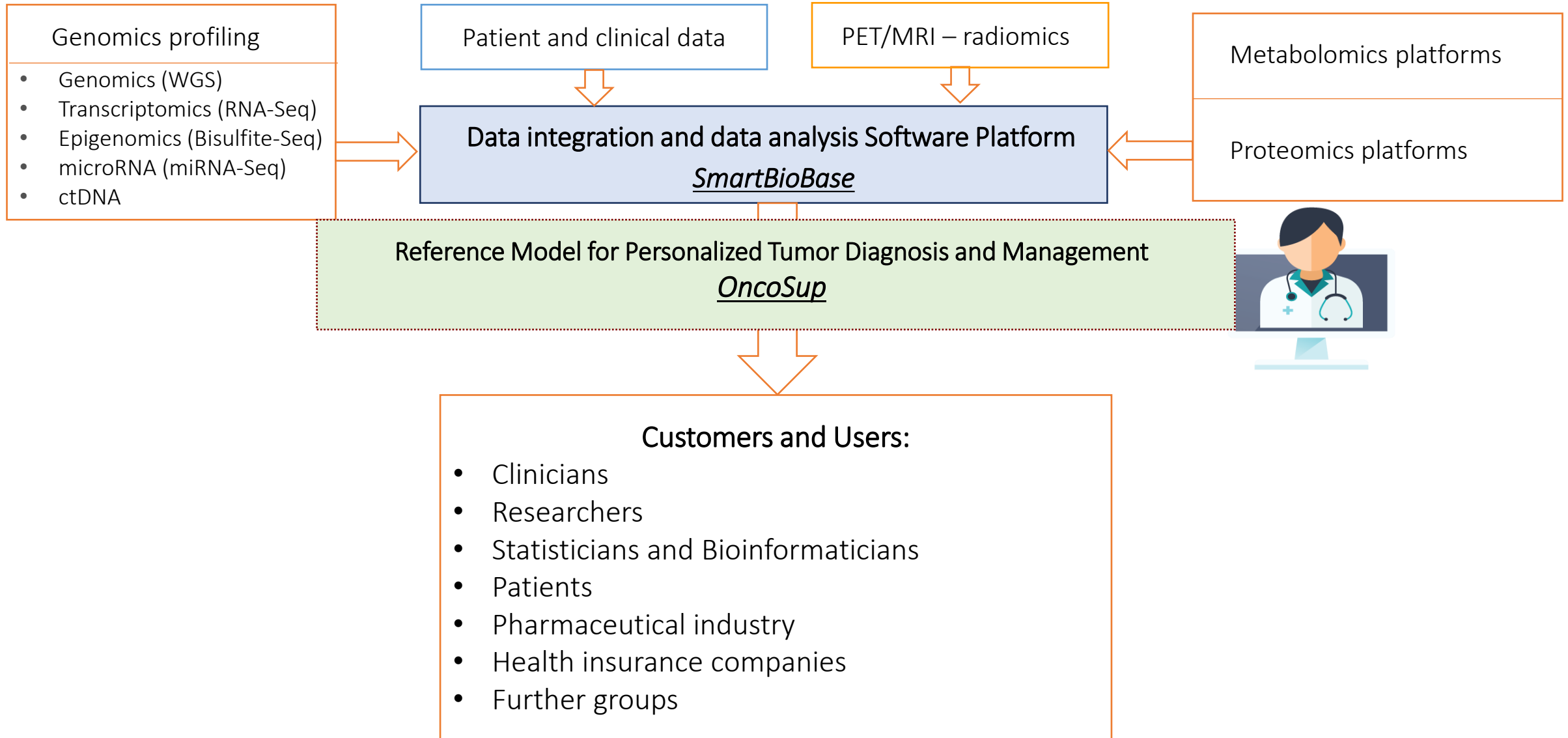
# **MOBIT Project (MOlecular Biomarkers for Individualized Therapy)**

- Creation a unique oncology biobank providing the service of samples:
  - \* central and peripheral tumor tissue
  - \* normal tissue
  - \* blood (whole blood, serum, plasma)
  - \* urine (supernatant, sediment)
- Development of software platform for collection, integration and analysis of -omics and clinical data for implementation of individualized therapy
- Development of personalized diagnostic procedures based on tumor heterogeneity and integrated genomics, transcriptomics, proteomics, metabolomics and PET/MRI imaging analysis
- Creation of reference model (and SOPs) for personalized tumor diagnosis and intervention with Non-Small Cell Lung Cancer as a model.

# The **MOBIT** approach



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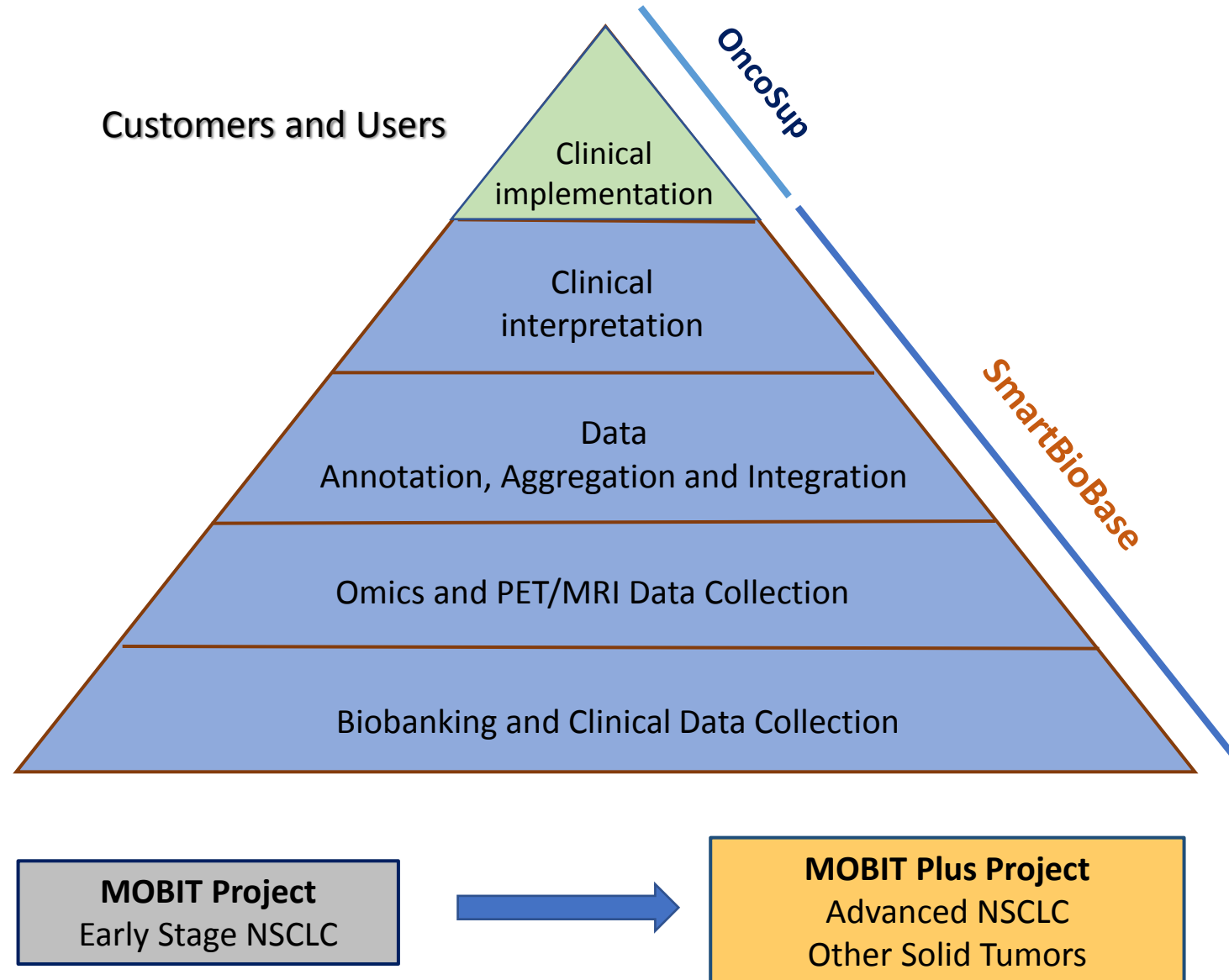




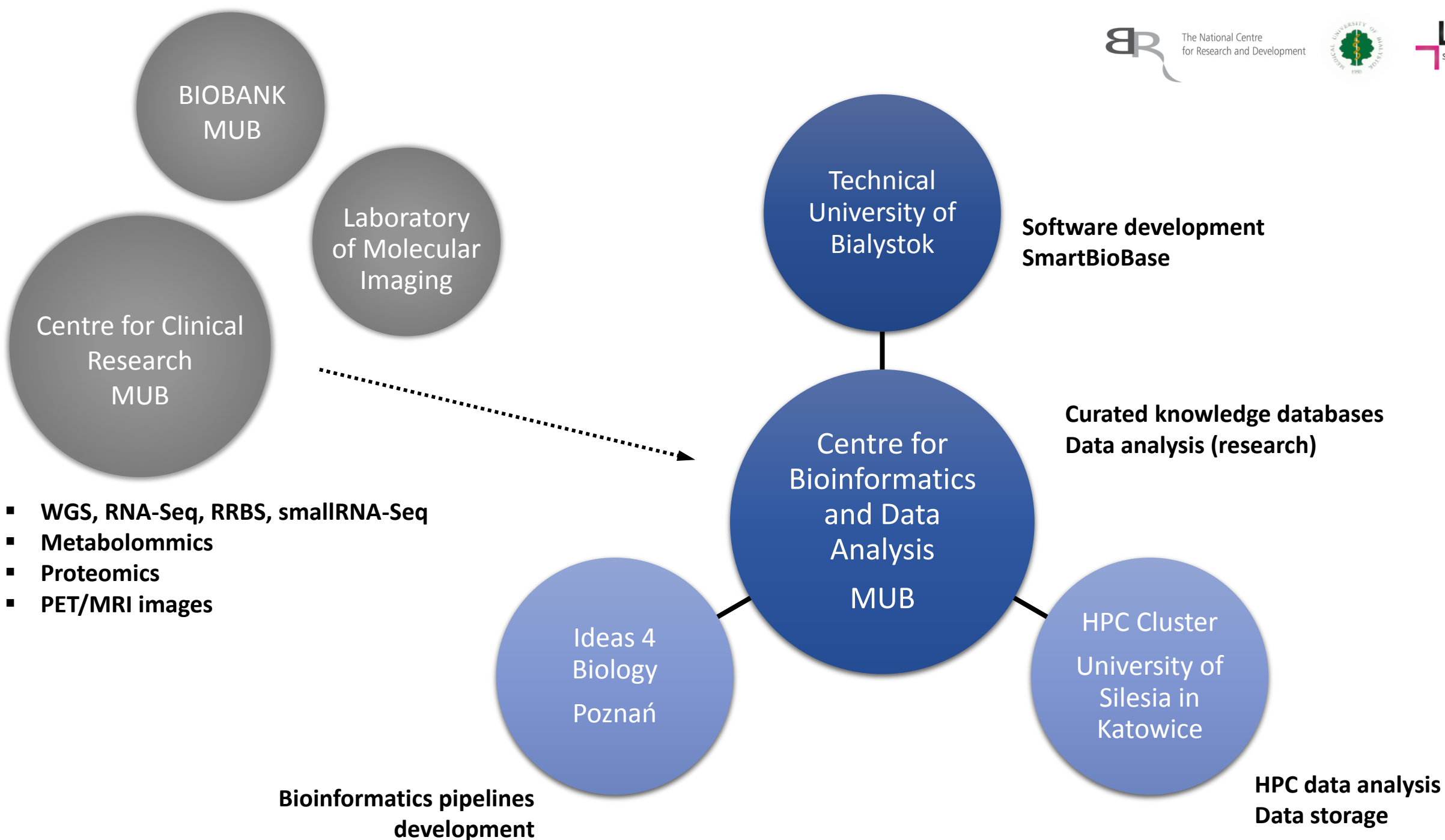
# The **MOBIT** approach



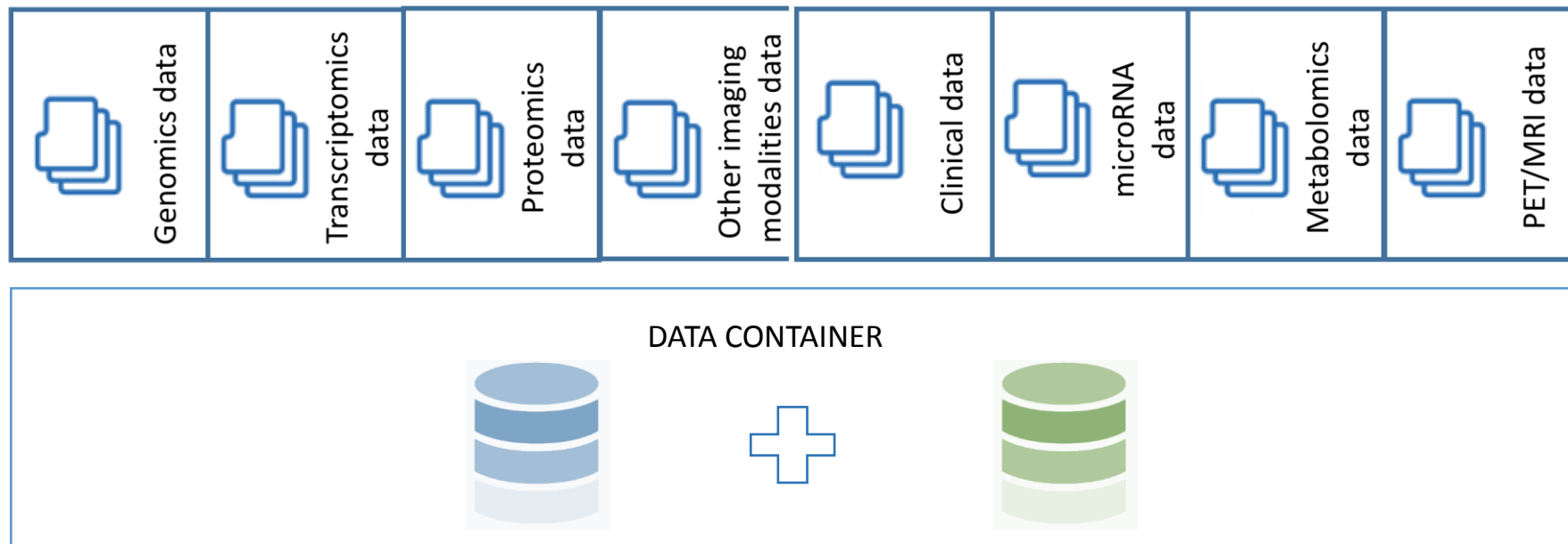
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Omics data, imaging data, questionnaires, other clinical data...



Data storage, management,  
processing and analysis:  
**SmartBioBase**

# SmartBioBase – key components

## Data Management

**„Manager” module** – supports patient management and related events, includes functionalities: defining patient groups, adding patients to groups, viewing patients data and associated events.

**„Calendar” module** – offers a preview of the action schedule defined for patients in the SmartBioBase; gives the ability to view patient actions in month, week, and day view and allows to modify critical parameters including start and end dates, times and status of events.

## Data Processing

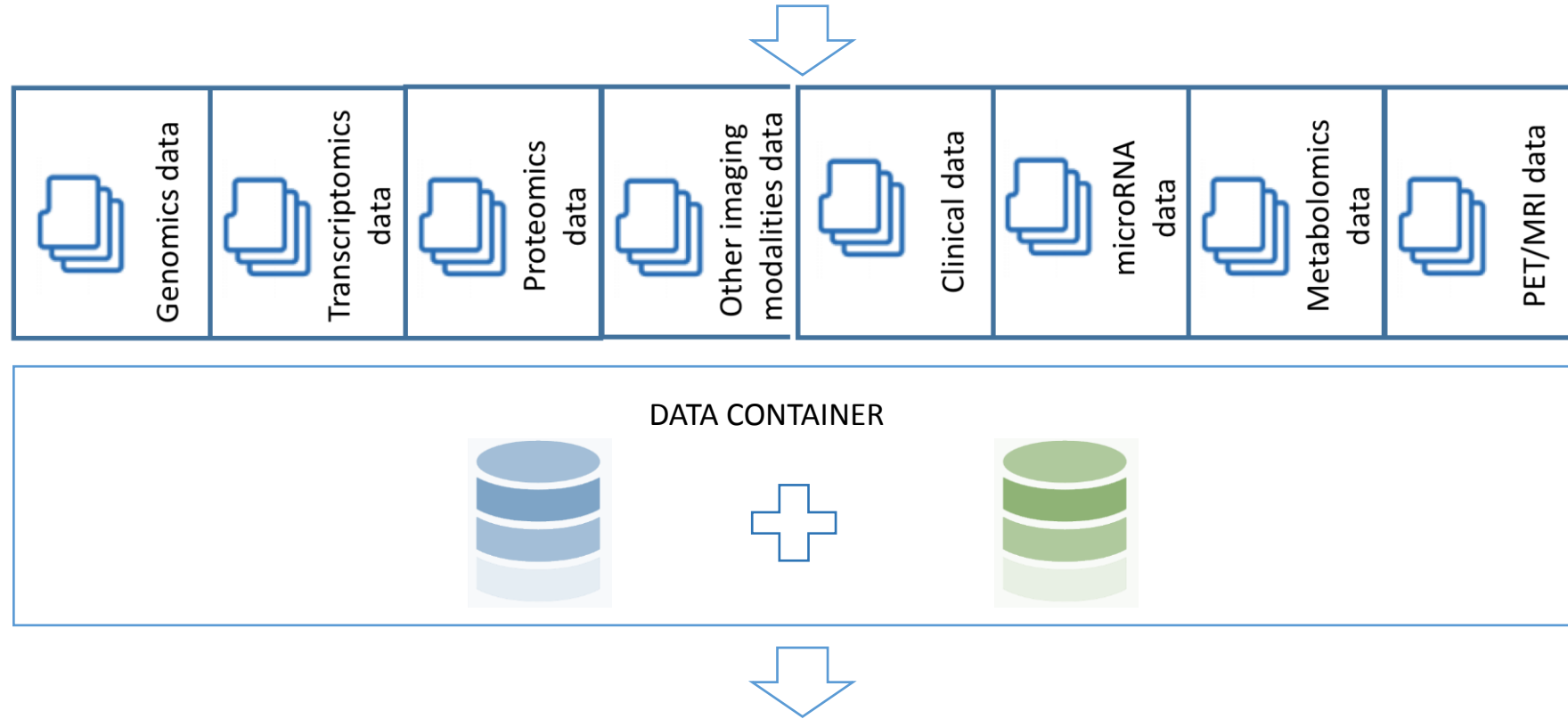
**„Data Migration” module** – to facilitate the migration and integration of data to SmartBioBase. It allows for interactive upload of genomics, metabolics, and imaging data (eg PET/ MRI).

**„Medical Imaging Data Viewer”** – provides access to patient image data stored in DICOM format. This component gives the ability to preview images directly from your web browser without installing additional plugins or applications.

## Data Integration and Analysis

- Modules for processing of raw genomics data based on developed bioinformatic pipelines
- Modules for integration of selected sets of collected data, including clinical data, processed genomics data, metabolomics data or image-based data
- Analytical tools for processing and analysis very large data sets in a distributed manner on the basis of potentially interesting patterns defined by the researchers

Omics data, imaging data, questionnaires, other clinical data...



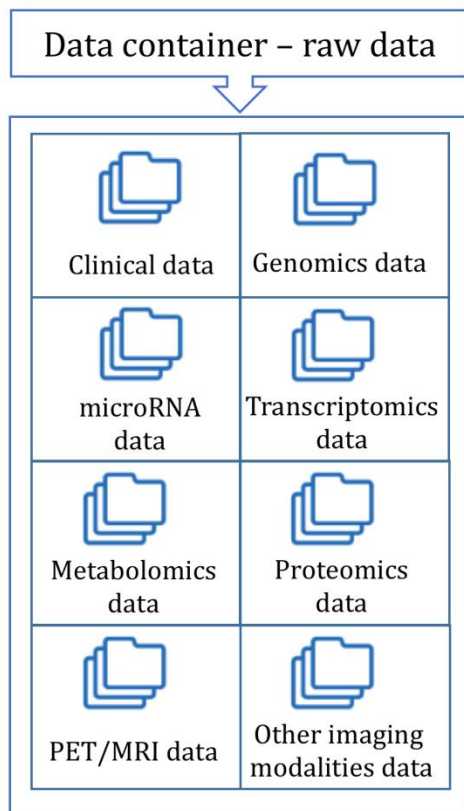
Data interpretation; support for diagnostic and therapeutic procedures

**OncoSup**

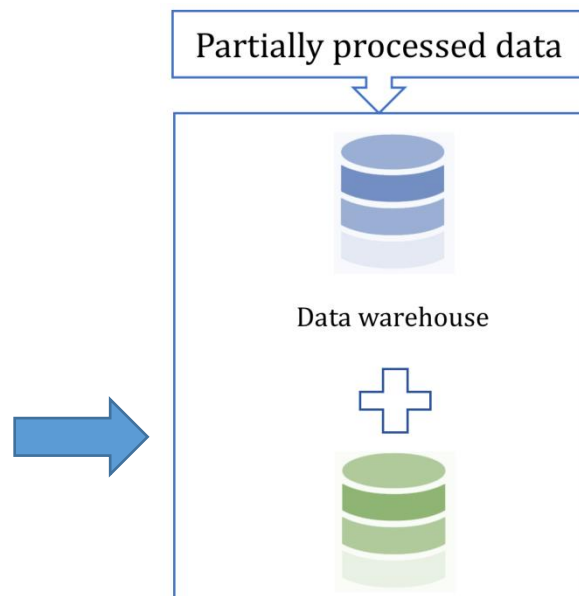
Data storage, management,  
processing and analysis:  
**SmartBioBase**



## Data sets



## SmartBioBase



## Formulation of diagnostic algorithms

**Clinicians/ Experts/ Advisors:**  
**Formulation of diagnostic queries in natural language**

**Bioinformaticians/informaticians:**  
**Processing of diagnostic queries**  
**- transformation into SmartBioBase queries**

**Expert teams:**  
Selection of the set of known cancer biomarkers, described in the literature and clinically verified

**Clinically actionable variants**  
Potentially actionable variants  
Biologically significant variants  
Cancer pathways variants

- Testing of diagnostic algorithm on MOBIT data
  - Reformulation of diagnostic algorithm
  - Reinforcement
- ❖ **Development of the ONCOSup service**

# Drugs for personalized therapy in lung cancer



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| Targeted oncogenic driver | FDA approved drugs                                                    | Drugs under study                                                                                                   | % NSCLC patients |
|---------------------------|-----------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|------------------|
| EGFR                      | Gefitinib, erlotinib, afatinib, osimertinib, bevacizumab, necitumumab | Dacomitinib, olmutinib (HM61713), ASP8273, nazartinib (EGF816), avitinib, PF-06747775, HS-10296                     | 10-15%           |
| VEGFR2                    | Ramucirumab                                                           |                                                                                                                     |                  |
| ALK                       | Crizotinib, ceritinib, alectinib, brigatinib                          | Ensartinib, entrectinib, lorlatinib                                                                                 | 3-7%             |
| ROS1                      | Crizotinib                                                            | Ceritinib, cabozantinib, entrectinib, lorlatinib                                                                    | 1-2%             |
| RET                       |                                                                       | RXDX-105, cabozantinib, vandetanib, sunitinib, sorafenib, alectinib, lenvatinib, nintedanib, ponatinib, regorafenib | 1-2%             |
| NTRK                      |                                                                       | Entrectinib, larotrectinib (LOXO-101), LOXO-195                                                                     | 1-2%             |
| BRAF                      | Dabrafenib and trametinib combination                                 | Vemurafenib, PLX8394, selumetinib                                                                                   | 1-4%             |
| HER2                      |                                                                       | Afatinib, dacomitinib, trastuzumab                                                                                  | 1-2%             |
| MET                       |                                                                       | Crizotinib, cabozantinib, capmatinib, MGCD265                                                                       | 4-5%             |
| KRAS                      |                                                                       | Selumetinib, trametinib, ARS853                                                                                     | 15-30%           |
| PD-1                      | Pembrolizumab                                                         |                                                                                                                     |                  |
| PDL-1                     | Atezolizumab                                                          |                                                                                                                     |                  |

# Prepared on the basis of the drug programs of the Polish Ministry of Health

Załącznik B.6.

## LECZENIE NIEDROBNOKOMÓRKOWEGO RAKA PŁUCA (ICD-10 C 34)

| ZAKRES ŚWIADCZENIA GWARANTOWANEGO                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
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| ŚWIADCZENIOBIORCY                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | SCHEMAT DAWKOWANIA LEKÓW W PROGRAMIE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | BADANIA DIAGNOSTYCZNE WYKONYWANE W RAMACH PROGRAMU                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>1. Kryteria kwalifikacji</b><br><b>1.1 Pierwsza linia leczenia</b><br><b>1.1.1 Leczenie przy wykorzystaniu substancji czynnej pemetreksed:</b><br>1) rozpoznanie gruczolakoraka, wielkomórkowego raka płuca lub nowotworu z przewagą wymienionych typów histologicznych;<br>2) zaawansowanie kliniczne w stopniach IIIB (z wyjątkiem przypadków, w których możliwe jest zastosowanie radiochemioterapii lub radioterapii) albo IV;<br>3) zmiany nowotworowe możliwe do zmierzenia;<br>4) w przypadku pojedynczej zmiany - umiejscowienie poza obszarem wcześniejszego napromieniania;<br>5) wiek powyżej 18 roku życia;<br>6) sprawność w stopniu 0-1 wg klasyfikacji Zubroda-WHO lub ECOG;<br>7) brak przerzutów w ośrodkowym układzie nerwowym pierwotnie albo po zastosowaniu wcześniejszego leczenia miejscowego oraz brak objawów ze strony ośrodkowego układu nerwowego, a także stała lub zmniejszana dawka kortykosteroidów przez ostatnie 4 tygodnie w przypadku konieczności ich stosowania;<br>8) nieobecność chorób współistniejących o istotnym klinicznie znaczeniu (niekontrolowane nadciśnienie tętnicze, niestabilna | <b>1. Pemetreksed</b><br>1.1 Zalecana dawka wynosi 500 mg/m <sup>2</sup> powierzchni ciała.<br>1.2 Podanie leku obejmuje 10-minutowy wlew dożylny w pierwszym dniu każdego 21-dniowego cyklu leczenia.<br>1.3 W dniu poprzedzającym zastosowanie pemetreksedu oraz w dniu zastosowania leku i w dniu następnym należy stosować lek z grupy kortykosteroidów w dawce równoważnej 4 mg deksametazonu podawanego doustnie 2 razy na dobę.<br>1.4 W celu ograniczenia objawów toksyczności pacjenci otrzymujący pemetreksed powinni również otrzymywać suplementację witaminową:<br>1) kwas foliowy lub produkt multiwitaminowy zawierający ten związek:<br>a) codziennie, przez cały cykl leczenia i przez 21 dni po podaniu ostatniej dawki pemetreksedu w dawce od 350 do 1000 mikrogramów doustnie,<br>b) w ciągu 7 dni poprzedzających zastosowanie pierwszej dawki pemetreksedu - co najmniej 5 dawek kwasu foliowego w ilości od 350 do 1000 mikrogramów doustnie;<br>2) witamina B12: | <b>1. Badania przy kwalifikacji do leczenia</b><br><b>1.1 Pemetreksed w pierwszej albo drugiej linii leczenia:</b><br>1) histologiczne lub cytologiczne potwierdzenie określonego typu niedrobnokomórkowego raka płuca zgodnie z kryteriami włączenia;<br>2) morfologia krwi z rozmazem;<br>3) oznaczenia stężenia kreatyniny;<br>4) oznaczenie stężenia bilirubiny;<br>5) oznaczenie aktywności aminotransferazy alaninowej;<br>6) oznaczenie aktywności aminotransferazy asparaginianowej;<br>7) oznaczenie aktywności fosfatazy zasadowej;<br>8) test ciążowy u kobiet w wieku rozrodczym;<br>9) badanie tomografii komputerowej klatki piersiowej z objęciem nadbrzusza lub klasyczne badanie RTG klatki piersiowej w przypadku zmiany dobrze mierzalnej, otoczonej przez prawidłowo upowietrzony miąższ płucny;<br>10) badanie tomografii komputerowej innej lokalizacji lub inne badania obrazowe (ultrasonografia - USG, rezonans magnetyczny - MR, scyntygrafia) w zależności od sytuacji klinicznej.<br><b>1.2 Gefitynib w pierwszej i drugiej linii leczenia:</b><br>1) histologiczne lub cytologiczne potwierdzenie określonego typu niedrobnokomórkowego raka płuca zgodnie z kryteriami włączenia;<br>2) potwierdzenie obecności aktywującej mutacji genu EGFR; | <b>1.2.4 Leczenie przy wykorzystaniu substancji czynnej ozymertynib:</b><br>1) rozpoznanie histologiczne lub cytologiczne raka gruczołowego (wraz z podtypami) lub raka niedrobnokomórkowego z przewagą raka gruczołowego lub raka niedrobnokomórkowego bez ustalonego typu (ang. not otherwise specified, NOS) z obecną mutacją aktywującą w genie kodującym receptor dla naskórkowego czynnika wzrostu (ang. skrót EGFR) w stadium miejscowego zaawansowania bez możliwości zastosowania leczenia lokoregionalnego lub w stadium rozsiewu;<br>2) progresja po zastosowaniu inhibitora kinazy tyrozynowej EGFR - TKI EGFR (gefitynib, erlotynib, afatynib) w pierwszej linii leczenia miejscowo zaawansowanego lub rozlanego niedrobnokomórkowego raka płuca;<br>3) potwierdzenie obecności mutacji T790M w genie kodującym receptor EGFR;<br>4) nieobecność cech progresji przerzutów w ośrodkowym układzie nerwowym po wcześniejszym leczeniu miejscowym (leczenie chirurgiczne lub radioterapia) oraz brak objawów neurologicznych i brak konieczności zwiększania dawki glikokortykosteroidów w ciągu ostatniego miesiąca przed włączeniem do programu;<br>5) istnienie możliwości oceny zmian nowotworowych wg kryteriów RECIST;<br>6) wiek powyżej 18 roku życia;<br>7) sprawność w stopniu 0-2 wg klasyfikacji WHO lub ECOG;<br>8) wykluczenie współwystępowania chorób o istotnym klinicznie znaczeniu (śródmiażdżowa choroba płuc, wrodzony zespół wydłużonego odstępu QTc, wydłużenie odstępu QTc w połączeniu z którymkolwiek z następujących zaburzeń: <i>torsade de pointes</i> , polimorficzny częstoskurcz komorowy, objawy ciężkich zaburzeń serca); |

# Prepared on the basis of the safety data sheets for medicinal products



## 3. POSTAĆ FARMACEUTYCZNA

Tabletka powlekana (tabletki).

TAGRISSO 40 mg tabletki

Beżowe, o średnicy 9 mm, okrągłe, dwuwypukłe tabletki, z wytłoczonym oznaczeniem „AZ” oraz „40” na jednej stronie oraz gładkie na drugiej stronie.

TAGRISSO tabletki 80 mg

Beżowe, o wymiarach 7,25 x 14,5 mm, owalne, dwuwypukłe tabletki, z wytłoczonym oznaczeniem „AZ” oraz „80” na jednej stronie oraz gładkie na drugiej stronie.

## 4. SZCZEGÓŁOWE DANE KLINICZNE

### 4.1 Wskazania do stosowania

Produkt leczniczy TAGRISSO jest wskazany do stosowania w leczeniu dorosłych pacjentów z miejscowo zaawansowanym lub rozsianym niedrobnokomórkowym rakiem płuca (NDRP) z obecną mutacją T790M w genie kodującym receptor dla naskórkowego czynnika wzrostu (ang. skrót EGFR).

### 4.2 Dawkowanie i sposób podawania

Leczenie produktem leczniczym TAGRISSO powinno zostać wdrożone przez lekarza doświadczonego w stosowaniu terapii przeciwnowotworowych.

Jeżeli rozważane jest zastosowanie produktu leczniczego TAGRISSO w leczeniu miejscowo zaawansowanego lub rozsianego NDRP, konieczne jest wykazanie obecności mutacji T790M w genie kodującym receptor dla EGF (EGFR). Status mutacji T790M w EGFR powinien zostać ustalony przy użyciu walidowanej metody testowej (patrz punkt 4.4).

#### Dawkowanie

Zalecana dawka wynosi 80 mg osymertynibu przyjmowanego raz na dobę do czasu progresji choroby lub wystąpienia nieakceptowalnej toksyczności.

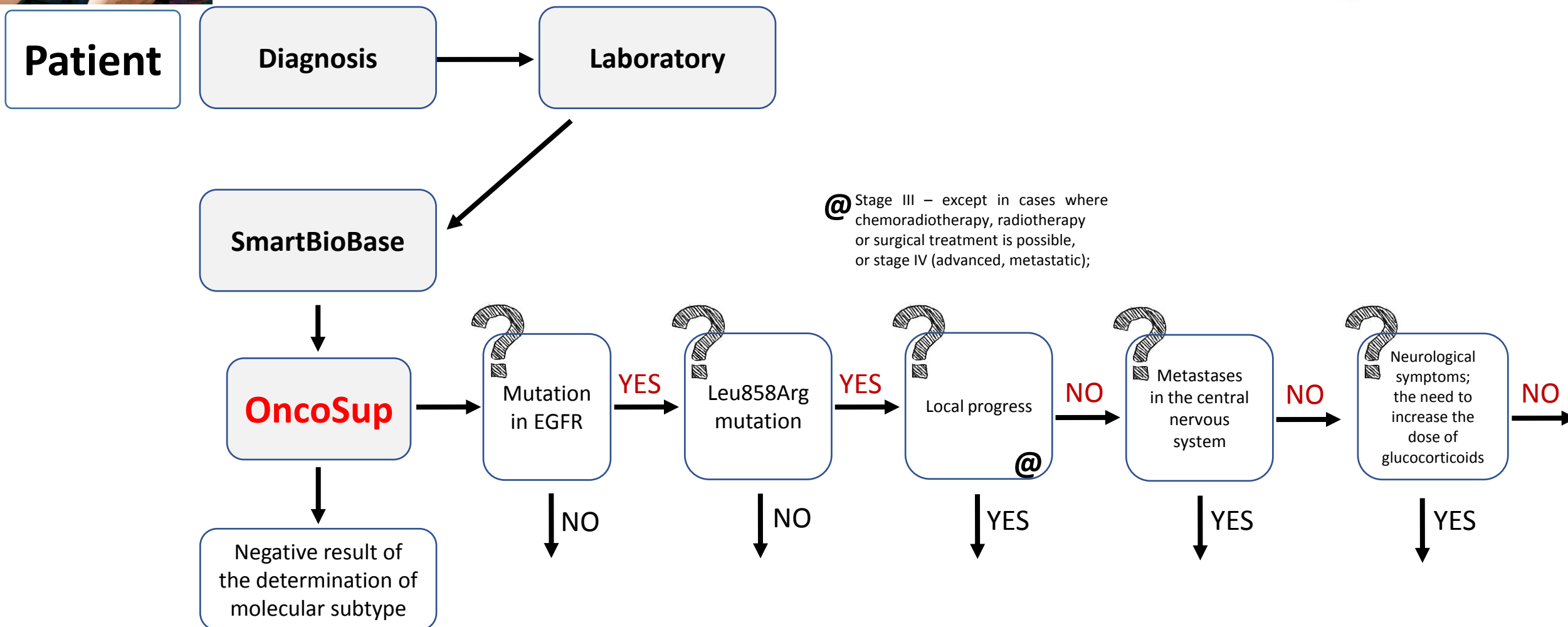




## Treatment in the first or second line



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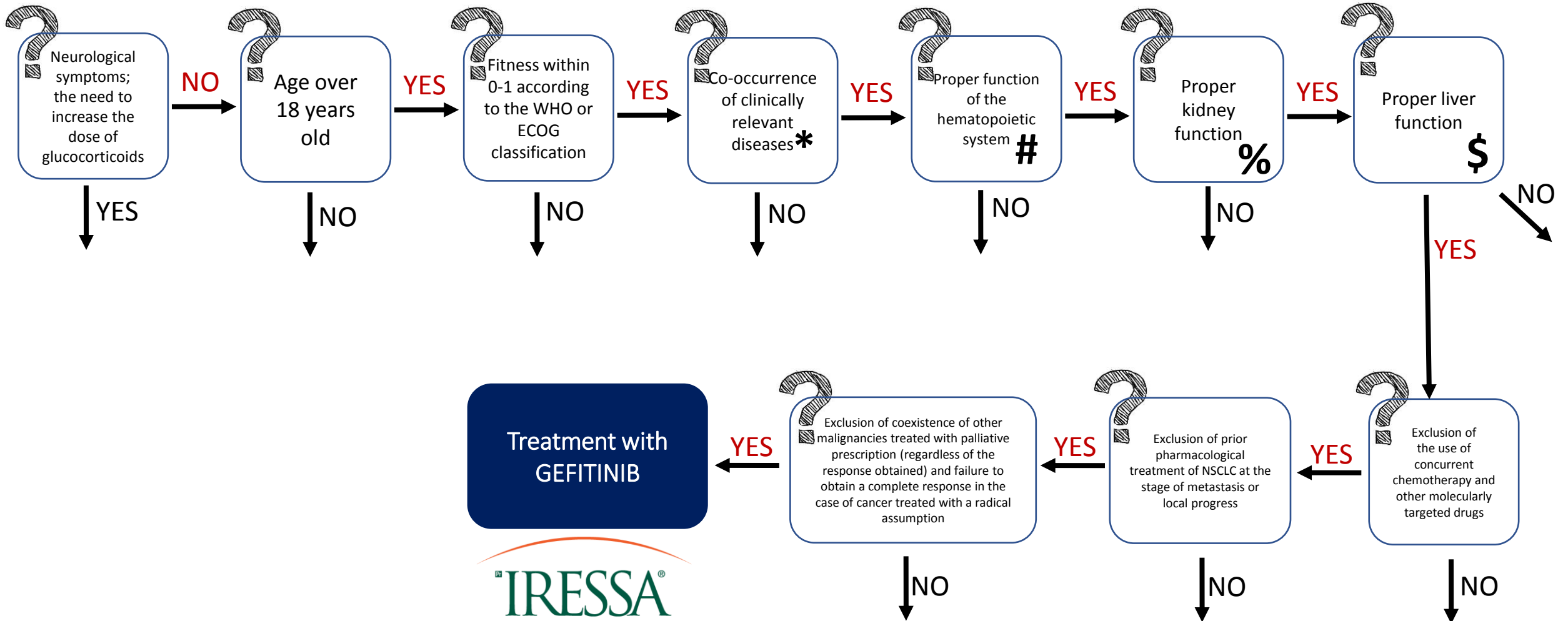


\* Uncontrolled hypertension, unstable coronary heart disease, myocardial infarction in the last year, ventricular arrhythmias requiring treatment

% Creatinine concentration doesn't exceed 1.5 times the upper limit of the norm

# Rules taking into account blood morphology examination

\$ Rules taking into account bilirubin concentration



Translation of approved diagnostic and therapeutic procedures of personalized therapy for **dynamic decision**  
support system within *OncoSup*

| LEK                                                   |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|-------------------------------------------------------|-------|--------|-----|--------------|-----------------------|-----------------------|--|---------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------|---------|-----------------------------------------------|--------------------------------------------|------|----------------|---------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-----|-------|------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------|-----|---------------------|------------------------|------|-----|------|---------------------------------------------------|----------|-----|-----------|---------------|----------|--|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|
| Substancja                                            | Nazwa | Status | NFZ | Typ raka     |                       |                       |  | Zaawansowanie |                                                                                     |                                                                                     |      | Mutacja |                                               |                                            |      | Linia leczenia |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     | Charakter nowotworu |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| W tej kategorii                                       |       |        |     | AND          |                       |                       |  | AND           |                                                                                     |                                                                                     |      | AND     |                                               |                                            |      | AND            |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku w danej kategorii                             |       |        |     | OR           |                       | OR                    |  | OR            |                                                                                     |                                                                                     | OR   |         | OR                                            |                                            | AND  |                |                                                                                                                                                   | AND                             |     | AND   |                                                                                                                                                      | AND                                                                                                     |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla drugiego poziomu warunku w danej kategorii  |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla trzeciego poziomu warunku w danej kategorii |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku                                               |       |        |     | TRUE         |                       | TRUE                  |  | TRUE          |                                                                                     |                                                                                     | TRUE |         | TRUE                                          |                                            | TRUE |                |                                                                                                                                                   | TRUE                            |     | TRUE  |                                                                                                                                                      | TRUE                                                                                                    |     | TRUE                |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Ozymertynib                                           |       |        |     | Tagrisso     | dopuszczon program le |                       |  |               | rak niedrob rak niedrob rak gruczolowy (wraz z i miejscowo i rozsiany               |                                                                                     |      |         | potwierdzona mutacja zgodna z refe druga      |                                            |      |                | progresja w w pierwszej linii stosowano gefitynib, erlotynib lub afatynib                                                                         |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Ankieta Follow-u Wpisujemy                            |       |        |     | Brak pola    | Brak pola             |                       |  |               | Ankieta Rap                                                                         |                                                                                     |      |         | Ankieta Rap                                   |                                            |      |                | Ankieta Raport patolog                                                                                                                            |                                 |     |       | Ankieta Rap                                                                                                                                          |                                                                                                         |     |                     | Ankieta Raport patolog |      |     |      | Ankieta Raport patologa: Pole "Anal Ankieta Foll  |          |     |           | Brak ściśle z |          |  |       | Ankieta Follow-up I/II/III/IV/V: "Leki i chemioterapia uzupełniająca" -> "Chemioterapia uzupełniająca" -> "Przebieg terapii" -> "Kurs 1" -> Pole "Schemat/leki" |  |  |  |
| W tej kategorii                                       |       |        |     | AND          |                       |                       |  | AND           |                                                                                     |                                                                                     |      | AND     |                                               |                                            |      | AND            |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     | AND                 |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku w danej kategorii                             |       |        |     | OR           |                       | OR                    |  | OR            |                                                                                     | OR                                                                                  |      | OR      |                                               | AND                                        |      |                |                                                                                                                                                   | OR                              |     |       |                                                                                                                                                      | OR                                                                                                      |     |                     |                        |      |     |      |                                                   | AND      |     | AND       |               |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla drugiego poziomu warunku w danej kategorii  |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     | AND  |         | AND                                           |                                            |      |                | AND                                                                                                                                               |                                 | AND |       | AND                                                                                                                                                  |                                                                                                         | AND |                     | AND                    |      | AND |      | AND                                               |          | AND |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla trzeciego poziomu warunku w danej kategorii |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                | OR                                                                                                                                                |                                 | OR  |       | OR                                                                                                                                                   |                                                                                                         | OR  |                     | AND                    |      | AND |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku                                               |       |        |     | TRUE         |                       | TRUE                  |  | TRUE          |                                                                                     | TRUE                                                                                |      | FALSE   |                                               | TRUE                                       |      | TRUE           |                                                                                                                                                   | FALSE                           |     | FALSE |                                                                                                                                                      | TRUE                                                                                                    |     | TRUE                |                        | TRUE |     | TRUE |                                                   | IF: TRUE |     | TRUE      |               | FALSE    |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     | Erlotinib    | Tarceva               | dopuszczon program le |  |               |                                                                                     | rak niedrob rak niedrob rak gruczol rak wielkok miejscowo : możliwe jes uogólnienie |      |         |                                               | potwierdzona mutacja aktywująca w pierwsza |      |                |                                                                                                                                                   | wcześniejszy wcześniejszy druga |     |       |                                                                                                                                                      | progresja ci pacjent < 7C pacjent > 7C chemioteraj działania niepożądane p zmiany now pojedyncza zmiana |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     | Erlotinib Te | Decyzja o d           |                       |  |               | program lekowy – B.6 Leczenie niedrobnokomórkowego raka płuc                        |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       | THEN: TRUE THEN: TRUE                                                                                                                                |                                                                                                         |     |                     |                        |      |     |      | THEN: TRUE                                        |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     | Varlota      | Decyzja o d           |                       |  |               | brak refundacji                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       | wcześniejszy wcześniejsza monoterapia                                                                                                                |                                                                                                         |     |                     |                        |      |     |      | umieszczenie poza obszarem wcześnie               |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| W tej kategorii                                       |       |        |     | AND          |                       |                       |  | AND           |                                                                                     |                                                                                     |      | AND     |                                               |                                            |      | AND            |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     | AND                 |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku w danej kategorii                             |       |        |     | OR           |                       | OR                    |  | OR            |                                                                                     | OR                                                                                  |      | OR      |                                               | AND                                        |      |                | AND                                                                                                                                               |                                 | AND |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   | OR       |     | OR        |               | AND      |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla drugiego poziomu warunku w danej kategorii  |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     | AND  |         | AND                                           |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla trzeciego poziomu warunku w danej kategorii |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku                                               |       |        |     | TRUE         |                       | TRUE                  |  | TRUE          |                                                                                     | TRUE                                                                                |      | FALSE   |                                               | TRUE                                       |      | TRUE           |                                                                                                                                                   | TRUE                            |     | FALSE |                                                                                                                                                      | TRUE                                                                                                    |     | FALSE               |                        |      |     |      |                                                   | IF: TRUE |     | IF: FALSE |               | IF: TRUE |  |       |                                                                                                                                                                 |  |  |  |
| Afatynib                                              |       |        |     | Giotrif      | dopuszczon program le |                       |  |               | rak niedrob rak niedrob rak gruczol rak wielkok miejscowo : możliwe jes uogólnienie |                                                                                     |      |         | potwierdzona mutacja aktywująca w pierwsza    |                                            |      |                | wcześniejsze leczenie farmakologiczne niedrobnokomórkowego raka płuca w stadium uogólnienia (obecność i obecność pi obecność pi pojedyncza zmiana |                                 |     |       | THEN: TRUE THEN: TRUE THEN: TRUE                                                                                                                     |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| W tej kategorii                                       |       |        |     | AND          |                       |                       |  | AND           |                                                                                     |                                                                                     |      | AND     |                                               |                                            |      | AND            |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     | AND                 |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku w danej kategorii                             |       |        |     | OR           |                       | OR                    |  | OR            |                                                                                     | OR                                                                                  |      | OR      |                                               | AND                                        |      |                | OR                                                                                                                                                |                                 |     |       | OR                                                                                                                                                   |                                                                                                         |     |                     | AND                    |      | AND |      | AND                                               |          | AND |           | AND           |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla drugiego poziomu warunku w danej kategorii  |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     | AND  |         | AND                                           |                                            |      |                | AND                                                                                                                                               |                                 | AND |       | AND                                                                                                                                                  |                                                                                                         | AND |                     | AND                    |      | AND |      | AND                                               |          | AND |           | AND           |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla trzeciego poziomu warunku w danej kategorii |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                | OR                                                                                                                                                |                                 | OR  |       | OR                                                                                                                                                   |                                                                                                         | OR  |                     | OR                     |      | AND |      | AND                                               |          | AND |           | AND           |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku                                               |       |        |     | TRUE         |                       | TRUE                  |  | TRUE          |                                                                                     | TRUE                                                                                |      | FALSE   |                                               | TRUE                                       |      | TRUE           |                                                                                                                                                   | FALSE                           |     | FALSE |                                                                                                                                                      | TRUE                                                                                                    |     | FALSE               |                        | TRUE |     | TRUE |                                                   | IF: TRUE |     | IF: TRUE  |               | IF: TRUE |  | FALSE |                                                                                                                                                                 |  |  |  |
| Gefitynib                                             |       |        |     | Iressa       | dopuszczon program le |                       |  |               | rak niedrob rak niedrob rak gruczol rak wielkok miejscowo : możliwe jes uogólnienie |                                                                                     |      |         | potwierdzona mutacja aktywująca w pierwsza    |                                            |      |                | wcześniejszy wcześniejszy druga                                                                                                                   |                                 |     |       | uprzednie s progresja ci pacjent < 7C pacjent > 7C chemioteraj działania niepożądane p zmiany now pierwsza lin druga linia druga linia współwyst nie |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       | THEN: TRUE THEN: TRUE                                                                                                                                |                                                                                                         |     |                     |                        |      |     |      | THEN: TRUE THEN: TRUE THEN: TRUE                  |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       | wcześniejszy wcześniejsza monoterapia                                                                                                                |                                                                                                         |     |                     |                        |      |     |      | zmiany now zmiany now obecność policzalnych zmian |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| W tej kategorii                                       |       |        |     | AND          |                       |                       |  | AND           |                                                                                     |                                                                                     |      | AND     |                                               |                                            |      | AND            |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     | AND                 |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku w danej kategorii                             |       |        |     | OR           |                       | OR                    |  |               |                                                                                     | OR                                                                                  |      | OR      |                                               | AND                                        |      | AND            |                                                                                                                                                   | AND                             |     | AND   |                                                                                                                                                      | AND                                                                                                     |     | AND                 |                        | AND  |     |      |                                                   | AND      |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla drugiego poziomu warunku w danej kategorii  |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      | AND     |                                               | AND                                        |      |                |                                                                                                                                                   | OR                              |     | OR    |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| ID/OR dla trzeciego poziomu warunku w danej kategorii |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                | OR                                                                                                                                                |                                 | OR  |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Warunku                                               |       |        |     | TRUE         |                       | TRUE                  |  |               |                                                                                     | TRUE                                                                                |      | TRUE    |                                               |                                            |      | TRUE           |                                                                                                                                                   | FALSE                           |     | FALSE |                                                                                                                                                      | TRUE                                                                                                    |     | TRUE                |                        | TRUE |     | TRUE |                                                   |          |     | TRUE      |               |          |  |       |                                                                                                                                                                 |  |  |  |
| Kryzotynib                                            |       |        |     | Xalkori      | dopuszczon program le |                       |  |               | niedrobnok gruczolakorak płuca                                                      |                                                                                     |      |         | miejscowo : uogólnienie na podstaw potwierdzo |                                            |      |                | potwierdzo potwierdzo potwierdzo druga                                                                                                            |                                 |     |       | trzecia progresja ci działania niepożądane po wcześniejszej terapii zostały wylczone do co najmniej 1. str zmiany nowotworowe możliwe do zmierzania  |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |
|                                                       |       |        |     |              |                       |                       |  |               |                                                                                     |                                                                                     |      |         |                                               |                                            |      |                |                                                                                                                                                   |                                 |     |       |                                                                                                                                                      |                                                                                                         |     |                     |                        |      |     |      |                                                   |          |     |           |               |          |  |       |                                                                                                                                                                 |  |  |  |



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| PROCES DECYZYJNY                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|-------|-------|--------------------------------|-------|------|------|------|----------------|------|------------------|------|------|------|-----------------|-----------------|---------|------|---|
| Neurologiczny stan pacjenta                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                |       |       |       | Czynność układu krwiotwórczego |       |      |      |      | Czynność nerek |      | Czynność wątroby |      |      |      | Kryteria RECIST | Pałac w trakcie | Wiek    | Płeć |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | AND   |       |       |                                |       | AND  |      |      | AND            |      | AND              |      |      | AND  | AND             |                 | AND     | AND  |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | AND   | AND   | AND   |                                | AND   | AND  | AND  | AND  | OR             | OR   |                  | AND  |      | AND  | AND             |                 | OR      | OR   |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      | OR               | OR   | OR   | OR   |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | FALSE | FALSE | FALSE |                                | TRUE  | TRUE | TRUE | TRUE | TRUE           | TRUE | TRUE             | TRUE | TRUE | TRUE | TRUE            |                 | TRUE    | TRUE |   |
| progresja przerz objawy neurolog dawka glikokortykosteroidów zos prawidłowa czyn liczba granulocyt liczba płytek ≥ 10 <sup>9</sup> /l stężenie hemoglobiny stężenie kreatyniny klirens kreatyniny stężenie bilirubiny stężenie bilirubiny aktywność transaminaz aktywność transaminaz i zasadach możliwości oceny jednoczesnej |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 | >18 lat | K    | M |
| emat/leki"                                                                                                                                                                                                                                                                                                                     | Ankieta Follow-up Ankieta ogólna: I Porównanie danych w Ankiecie ogólnej z danymi w Ankiecie wyniki k Ankieta wyniki k Ankieta wyniki k Ankieta wyniki k Brak pola Ankieta wyniki k Ankieta wyniki k Ankieta wyniki k Ankieta wyniki k Brak pola Klikamy "Kod pa Klikamy "Kod pa Klikamy "Kod pa                                               |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | AND   |       |       |                                |       | AND  |      |      | AND            |      | AND              |      | AND  | AND  | AND             | AND             | AND     | AND  |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | AND   | AND   | AND   | AND                            |       | AND  |      |      | AND            | AND  | AND              |      | AND  | AND  | AND             | AND             | OR      | OR   |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      | OR               | OR   |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | FALSE | FALSE | FALSE | FALSE                          |       | TRUE |      |      | TRUE           | TRUE | TRUE             | TRUE | TRUE |      | TRUE            | FALSE           | TRUE    | TRUE |   |
| przerzuty w ośrodkową progresję przerz objawy neurolog dawka glikokortykosteroidów zos prawidłowa czynność                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 | >18 lat | K    | M |
| n wcześniejszego napromieniania                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | AND   |       |       |                                |       | AND  |      |      | AND            |      | AND              |      | AND  | AND  | AND             | AND             | AND     | AND  |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | OR    | OR    | AND   | AND                            |       | AND  |      |      | OR             | OR   | AND              |      | OR   | AND  | AND             | AND             | OR      | OR   |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  | OR   | OR   |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | FALSE | FALSE | FALSE | FALSE                          |       | TRUE |      |      | TRUE           | TRUE | TRUE             | TRUE | TRUE |      | TRUE            |                 | TRUE    | TRUE |   |
| a                                                                                                                                                                                                                                                                                                                              | przerzuty w ośrodkową progresję przerz objawy neurolog dawka glikokortykosteroidów zos prawidłowa czynność                                                                                                                                                                                                                                     |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
| VD                                                                                                                                                                                                                                                                                                                             | AND                                                                                                                                                                                                                                                                                                                                            | AND   | AND   | AND   | AND                            |       | AND  |      |      | AND            |      | AND              | AND  | AND  | AND  | AND             | AND             | OR      | OR   |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | OR    | OR    |       |                                |       |      |      |      |                |      |                  | OR   | OR   |      |                 |                 |         |      |   |
| LSE                                                                                                                                                                                                                                                                                                                            | TRUE                                                                                                                                                                                                                                                                                                                                           | FALSE | FALSE | FALSE | FALSE                          |       | TRUE |      |      | TRUE           |      | TRUE             | TRUE | TRUE |      | TRUE            |                 | TRUE    | TRUE |   |
| twąstę nieuzyskani przerzuty w ośrodkową progresję przerz objawy neurolog dawka glikokortykosteroidów zos prawidłowa czynność                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 | >18 lat | K    | M |
| nych zmian niemierzalnych                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | AND   |       |       |                                |       | AND  |      |      | AND            |      | AND              |      | AND  |      |                 | AND             | AND     | AND  |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | OR    |       | OR    |                                |       | AND  | AND  | AND  |                | AND  | AND              | AND  |      |      |                 | AND             | OR      | OR   |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       | AND   | AND   | AND                            | AND   |      |      |      |                |      |                  | OR   | OR   |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                | FALSE | TRUE  | TRUE  | TRUE                           | FALSE | TRUE | TRUE | TRUE |                | TRUE | TRUE             | TRUE | TRUE |      |                 | TRUE            | TRUE    | TRUE |   |
| nia                                                                                                                                                                                                                                                                                                                            | obecne przerzut obecne przerzut zastosowano wcześniejsze stan neurologiczny konieczność stosowania prawidłowa czyn liczba granulocytów liczba trombocytów większa lub równa 10 <sup>9</sup> /l stężenie kreatyniny klirens kreatyniny stężenie bilirubiny aktywność transaminaz aktywność transaminaz i zasadach możliwości oceny jednoczesnej |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |
|                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                |       |       |       |                                |       |      |      |      |                |      |                  |      |      |      |                 |                 |         |      |   |



[illegible]

# OMICS analysis



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## **WGS (Whole Genome Sequencing)**

- 144 samples analyzed
- complete results of 72 patients samples

**TMB prognostic models, variant and mutation frequency**

## **RNA-Sequencing**

- 350 samples analyzed

**Random Forest-based tool for diagnostic and prognostic decision support**

## **RRBS (Reduced representation bisulfite sequencing)**

- 350 samples analyzed

**New epigenetic prognostic markers**

## **Small RNA sequencing**

- 175 samples analyzed

**Liquid biopsy microRNA prognostic signature**

**Patient**



**Diagnosis**



**Laboratory**



Patient data (questionnaire), Standard laboratory tests, Raw omics data (NGS), Histopathology data  
PET/MRI imaging

## SmartBioBase + OncoSup

**Primary data analysis**



Results of NGS data analysis

➤ **Technical report on NGS data**

**Data integration**

(data + knowledge databases)



Molecular profiling  
Identification of potentially actionable variants  
Prioritytization of clinically actionable variants with approved therapeutic actions  
Identification of therapeutics and therapies

➤ **Static report based on molecular profiling**

**Data interpretation**

(molecular profile + diagnostic and prognostic models + knowledge databases)



Diagnostic decision support system  
Pniagnostic decision support system

➤ **Diagnostic and prognostic decision support**

**Data interpretation+**

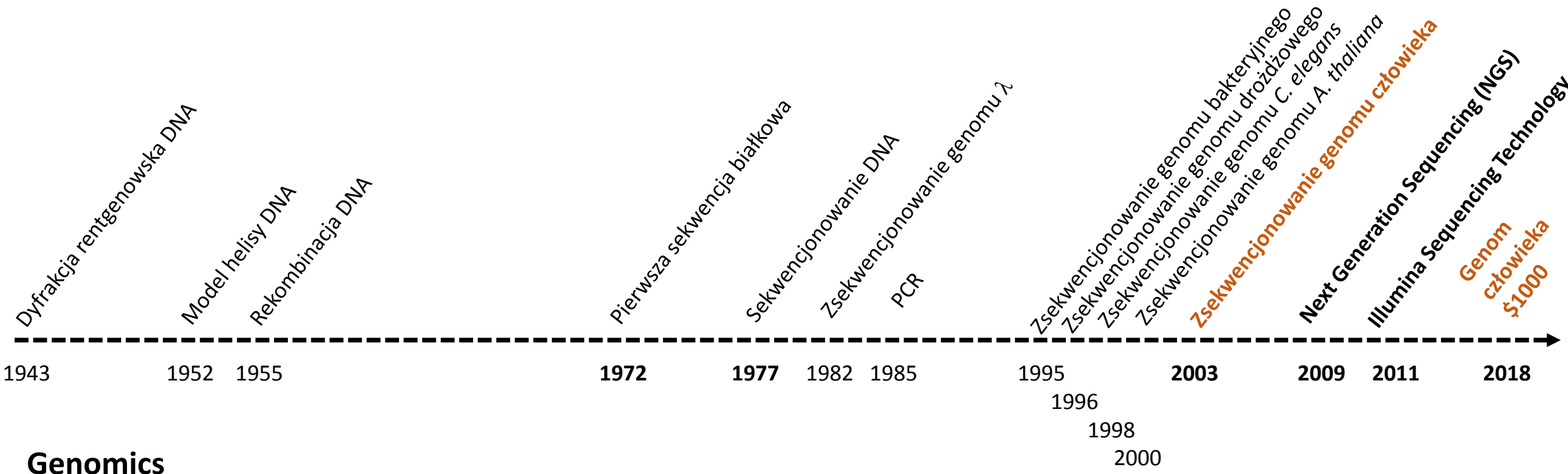
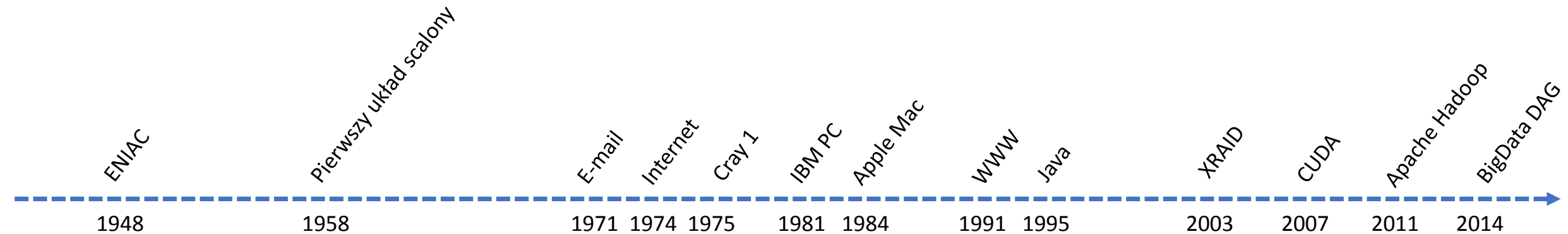
(molecular profile+ available therapies+ other diagnostic data)



Recomendation of therapeutic proces based on molecular profile and other clinically valuable diagnostic data and available therapies

➤ **Dynamic decision support system**

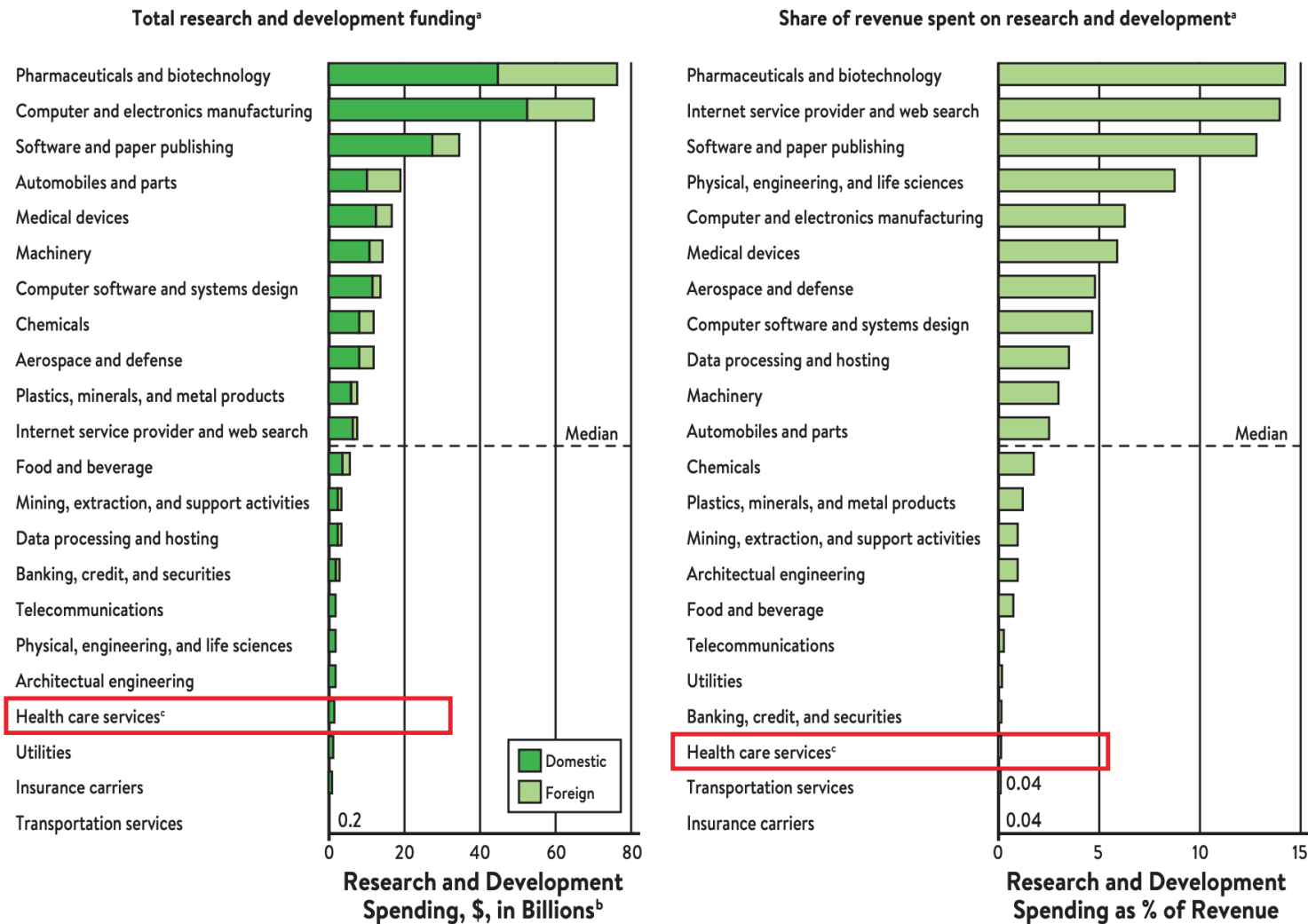






## THE FUTURE OF HEALTH SERVICES RESEARCH

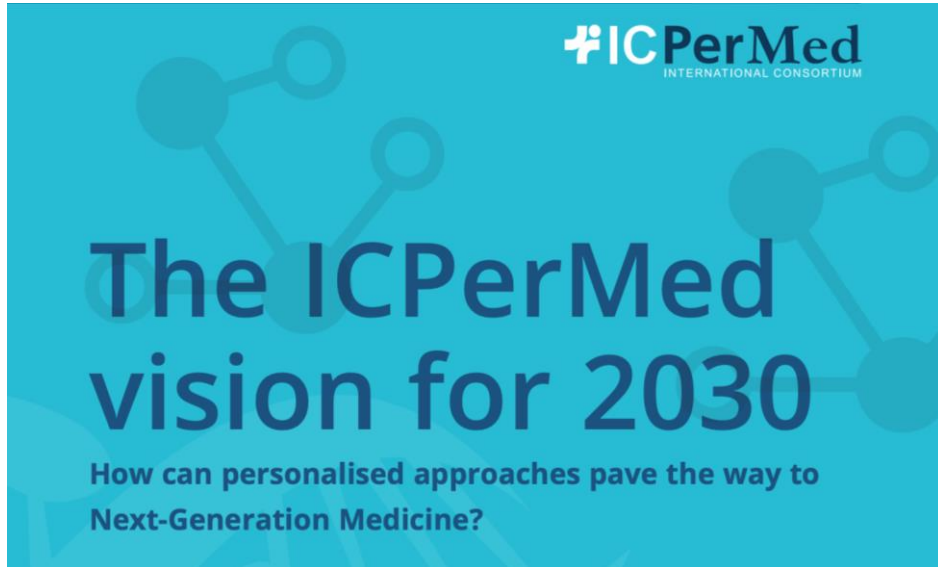
ADVANCING HEALTH SYSTEMS RESEARCH  
AND PRACTICE IN THE UNITED STATES



**FIGURE 2-1 |** Health care services represent a small share of industrial research-and-development funding (left) and percentage of revenues spent on research and development (right) by US-based companies

SOURCE: Moses et al. 2015

[https://nam.edu/wp-content/uploads/2018/11/The-Future-of-Health-Services-Research\\_web-copy.pdf](https://nam.edu/wp-content/uploads/2018/11/The-Future-of-Health-Services-Research_web-copy.pdf)



## 2. ICPerMed Perspectives for Personalised Medicine in 2030

The perspectives that ICPerMed will address going forward are:

### **Perspective 1: Informed, empowered, engaged, and responsible citizens**

- a) All health-related data is controlled by the citizen.
- b) Health data input and access is controlled, supported, and monitored by the citizen.
- c) Easily accessible, reliable, and understandable sources of medical information are available, e.g. tested and approved Apps or internet tools.

### **Perspective 2: Informed, empowered, engaged, and responsible health providers**

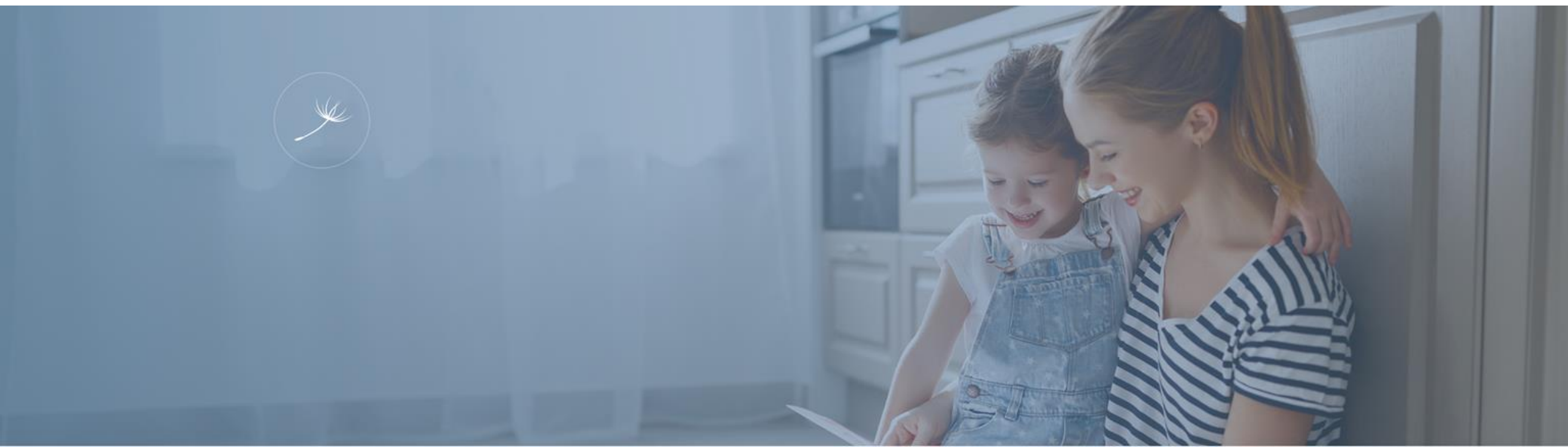
- a) The safe (i.e., privacy-protective), responsible, and optimal use of health-related information and research results to identify the best health promotion, disease prevention, diagnosis, and treatment options for each patient, supported by suitable information and communication technology (ICT) solutions, has become routine in the clinic.
- b) Personalised treatment of multi-morbid patients, non-responders, the elderly, and other vulnerable groups, with the minimisation of adverse effects, is routine, requiring clinical decisions by multidisciplinary teams and the development of novel health-related professions to support personalised healthcare.
- c) The education of healthcare professionals has adopted the interdisciplinary aspects of PM, such as the use of ICT and policy/regulatory questions, including equity and ethics, to access and adequately utilise all available information.
- d) Clinicians and researchers work closely to support the rapid development and implementation of personalised clinical solutions.

### **Perspective 3: Healthcare systems that enable personally tailored and optimised health promotion, prevention, diagnosis, and treatment for the benefit of citizens and patients**

- a) Equitable access to personalised healthcare for all citizens, independently of socioeconomic status, age, gender, ethnicity, and insurance coverage, is a reality.
- b) Personalised healthcare services are optimised in terms of effectiveness and equity.
- c) Fair and reasonable allocation of resources within healthcare systems is consistent with societal values.
- d) Secure health and related data flow from citizens and healthcare systems to regulatory authorities and researchers, among others, is in place.

### **Perspective 4: Availability and optimal use of health-related information for optimised treatment, care, prevention, and research**

- a) A combination of imaging and diagnostic, genomic and other molecular data, and information on lifestyle, environment, and socioeconomic status, displayed in electronic health records (EHRs), are used by healthcare providers and researchers for more efficient healthcare.
- b) Harmonised solutions to ensure data privacy, safety, and security are used in a transparent way throughout the health-data management process.
- c) Optimised treatment and prevention benefit citizens, while minimising costs and risks.



**Imagene.me** was born in the mind of life and data science **researchers** thrived by the potential of the latest groundbreaking technology and science achievements in the area of human genomics, personalized medicine and large-scale data analysis.

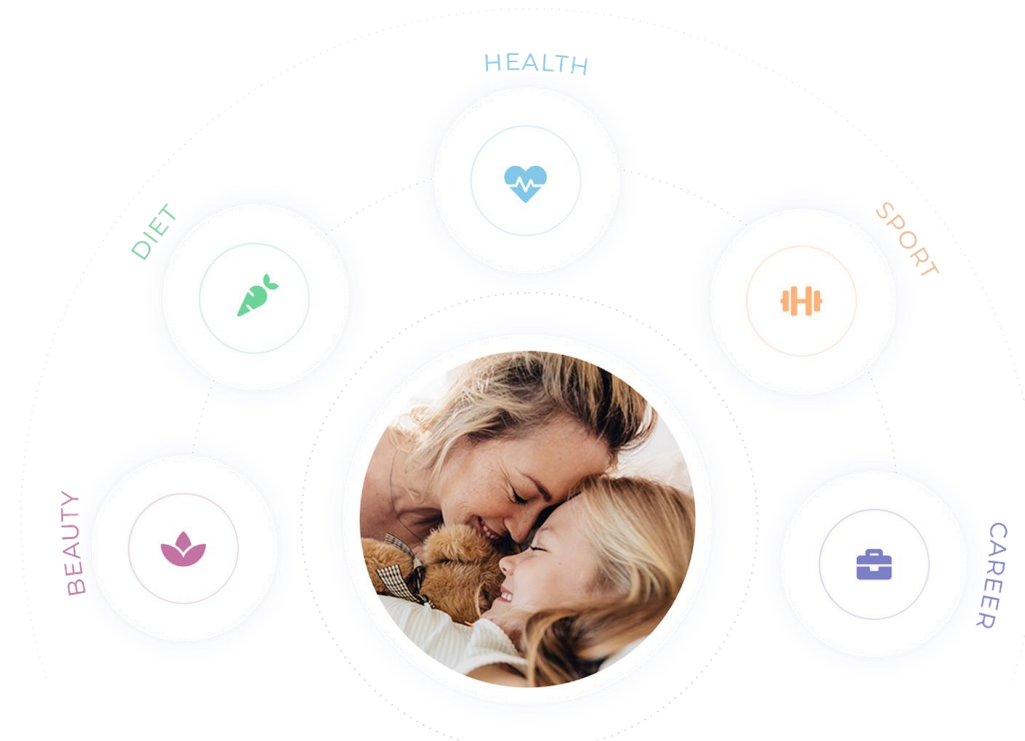
Imagene.me – 46 highly experienced domain professionals in the area of :

- Biotechnology (12)
- Human genetics and genomics (4)
- Medicine (3)
- Bioinformatics (3)
- Software engineers and business analysts (13)
- Artificial Intelligence and data analysis (6)
- Data safety (2)
- UX/UI and psychology (3)

# Imagene.me

Our mission is to increase the awareness and engagement of people in personal health management on a population scale. Imagene.me targets the transformation of complex biomedical and behavioral data into **personalised insight**.

**Vision:** provide self-improving, IA-powered personal assistant aiding **informed choices in the area** of health, life style, diet or physical activity.

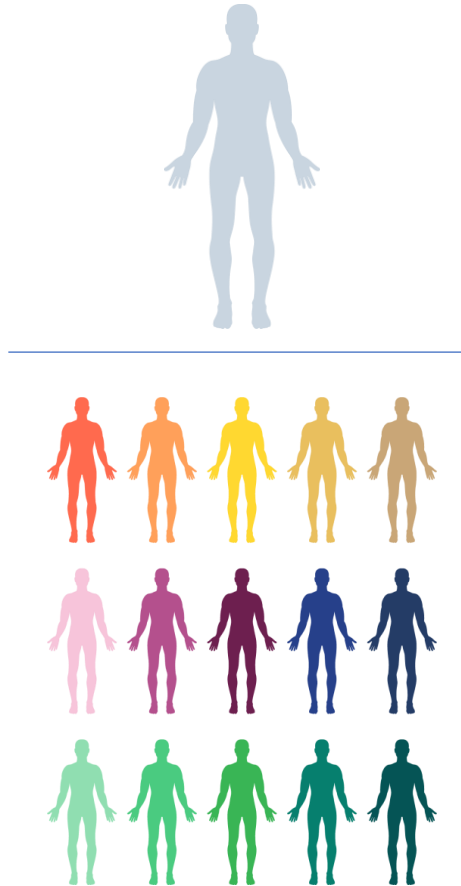


Personal data, clinical records (electronic health records, patients' socio-demographic), medical care pathways data

(EHR)



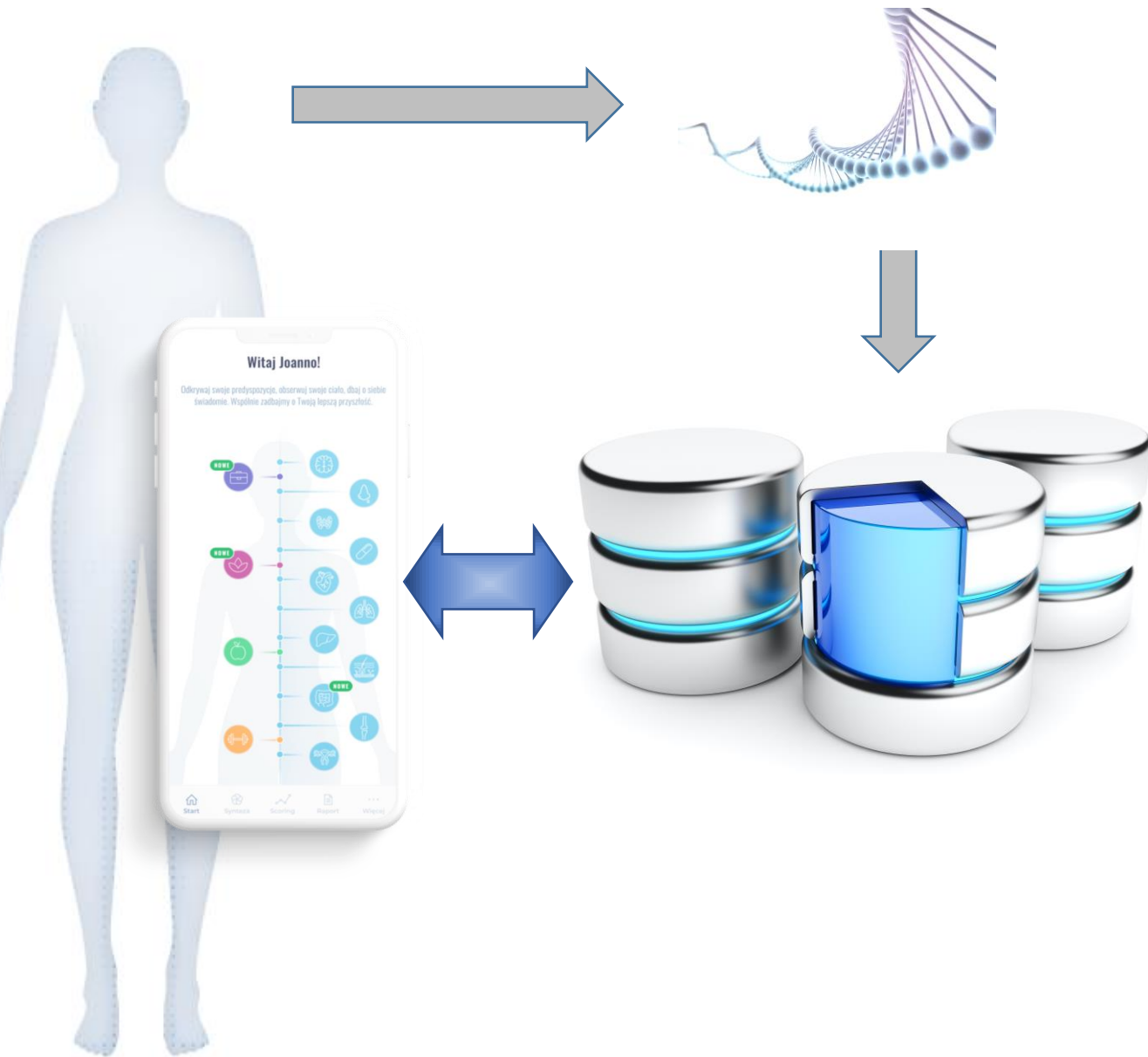
Genomics, behavioral, environmental data



**10 years of experience in effective implementation of analytical solutions based on AI on the medical services market in the USA**

Imagene.me myLife





Imagene.me myLife

## THE CONCEPT is simple

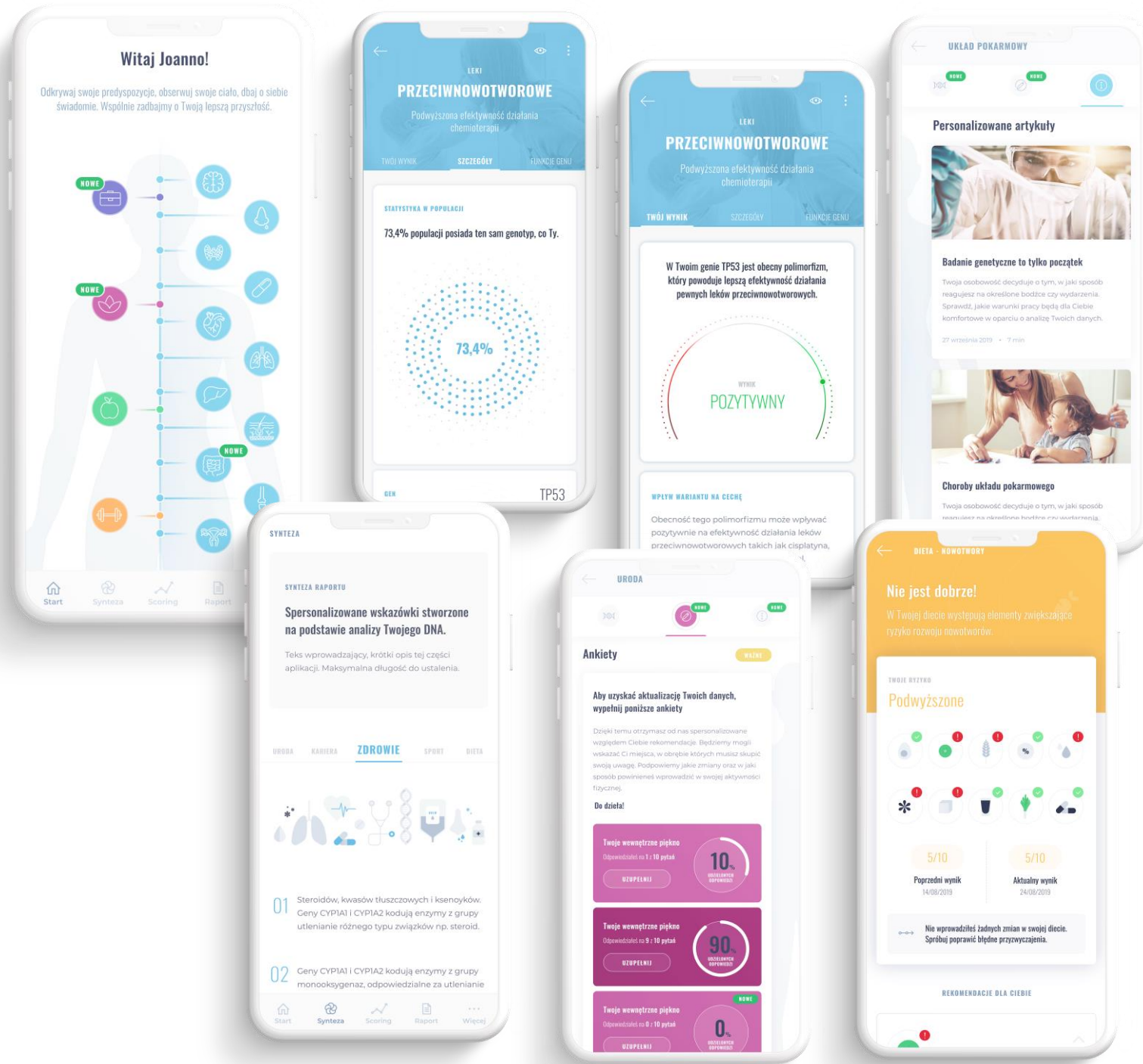
We receive a **saliva sample**, we decipher DNA variants and send back to our customer a personalised and simple information based on his DNA. That's how the story begins.

We know that what our genes determine, is influenced largely by our lifestyle.

Therefore we establish an **app-based "conversation"** with the customer to get what we need to **assist** him better in his choices. That's how we're building the value.

**THE POTENTIAL** is high. Questionnaires and voluntary activity monitoring feed the system, improving the quality of personalized **advises, suggestions or warnings**. We are ready to add additional important layers of information, such as electronic health records, medical devices or other - still to be imagined - to improve the accuracy of our advises.

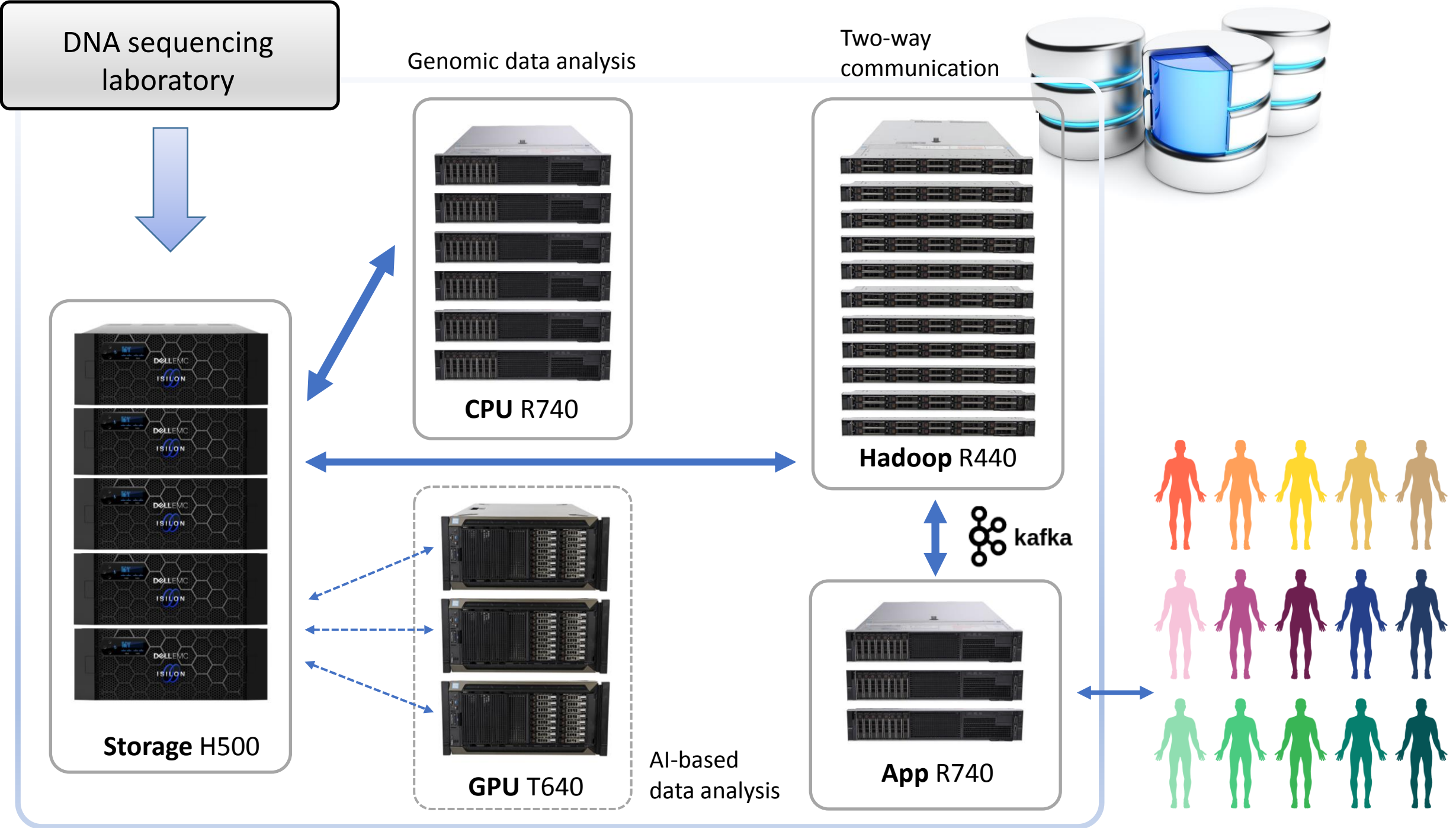
Imagine.me myLife

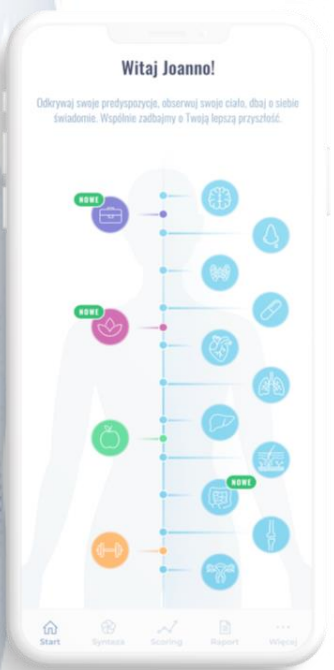


## THE CORE of our solution

An AI-powered BigData system connects phenotypical and behavioral data collected per person over the time with his genomic profiles. Then, at a population scale, the system analyses multivariate associations and addresses valuable questions and problems by making generalized models. A new person joining the imagine.me community is profiled and their respective outcomes (corrected predictions, risks and risk-minimizing actions) are provided.



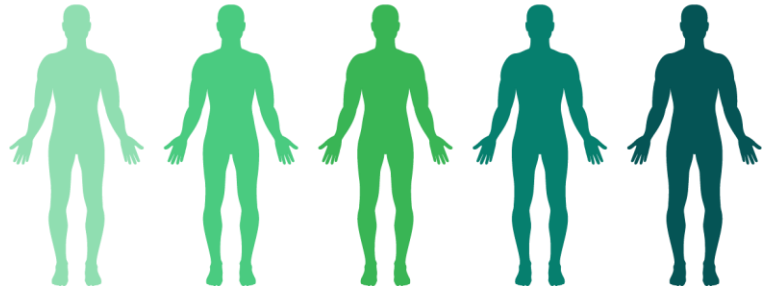
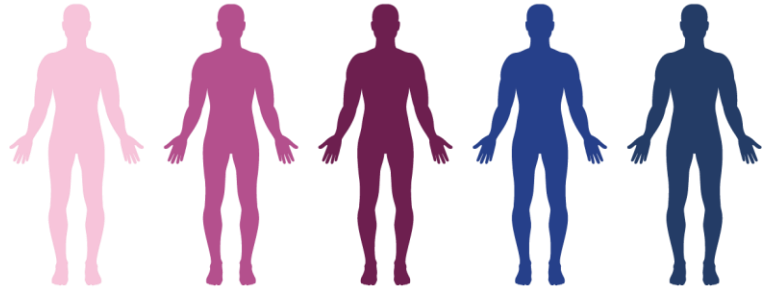
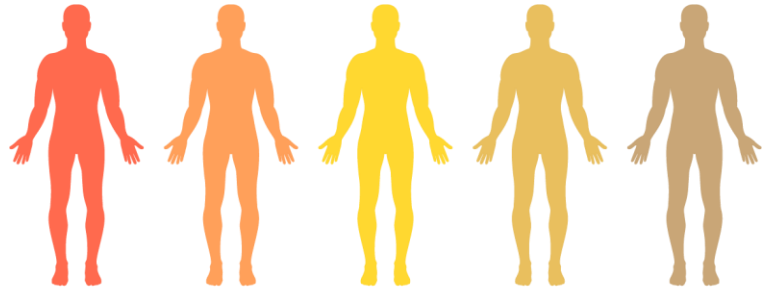




- Whole exome- or whole genome sequencing
- Detailed, life-long updated genetic predisposition report
- Other engagement-increasing features (dynamic scoring system)

### In-app two-way communication:

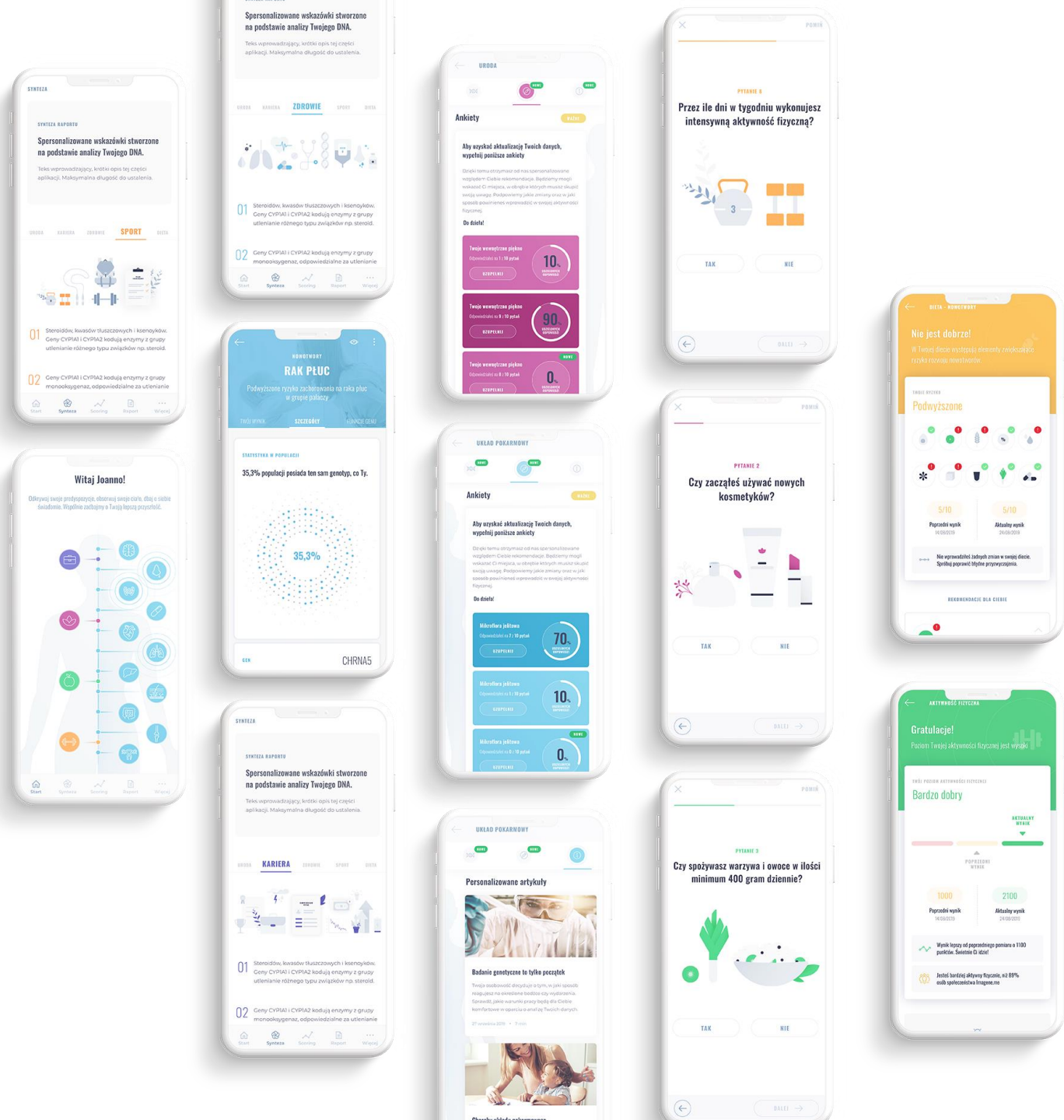
- Acquisition of behavioral data
- Motivation-related mechanisms
- Personalized guidelines for behavioral intervention



- Significance analysis/ validation of known disease associations
- Identification of new disease associations
- Identification of behavioral risk factors
- Population variability analysis
- Prediction of future health system load
- Awareness increment
- Motivation increment
- Participation and responsibility increment



# Imagene.me myLife

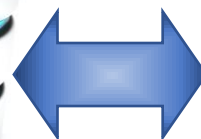
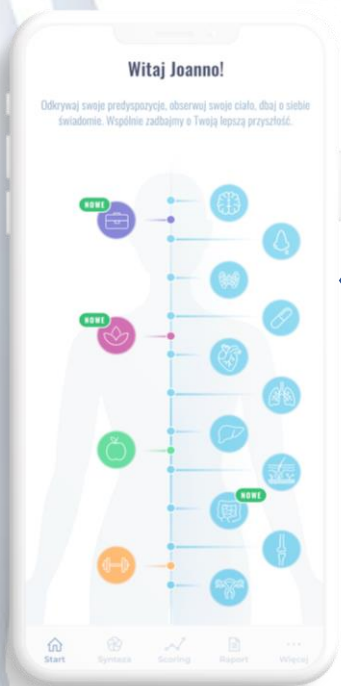




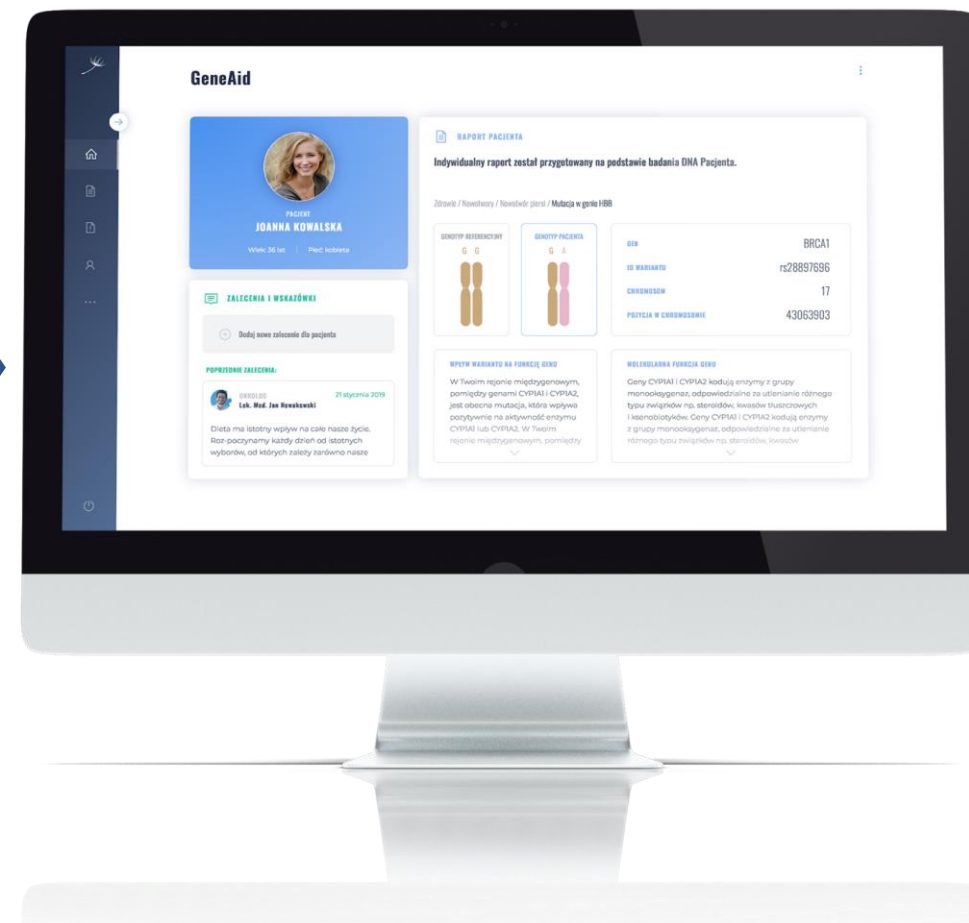
Healthcare  
Precision Nutrition  
Sport Coaching



myLife



Scientific community



# myLife

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