SAPIEN
BIOSCIENCES

Biobank-enabled Clinical Diagnostics and Personalized Medicine

CATALYZING DRUG AND BIOMARKER DEVELOPMENT USING

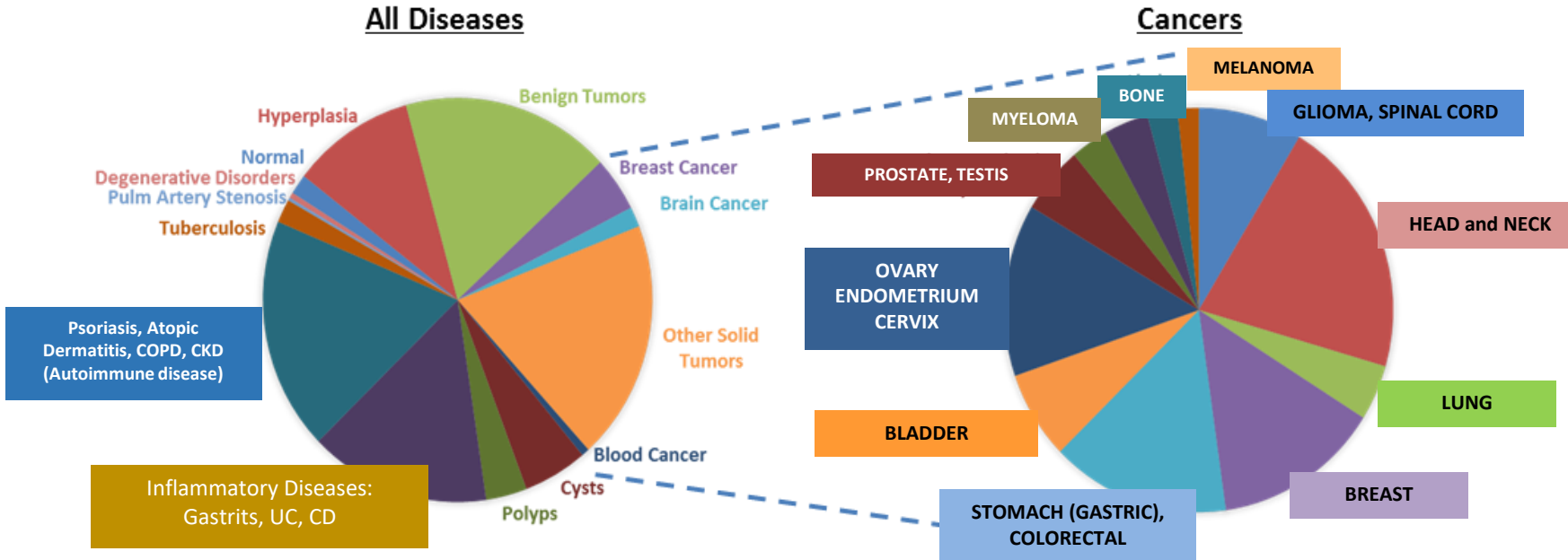*INSIGHTS FROM HUMAN PATIENT SAMPLES AND CLINICAL DATA*

"FROM THE PATIENT >> TO THE PATIENT"

www.sapienbio.co.in

Sapien is Among the World's 10 Largest, Multi-Diseases Biobank

Biobank Sample/Disease Diversity

All Diseases

- Benign Tumors
- Hyperplasia
- Normal
- Degenerative Disorders
- Pulm Artery Stenosis
- Tuberculosis
- Breast Cancer
- Brain Cancer
- Psoriasis, Atopic Dermatitis, COPD, CKD (Autoimmune disease)
- Other Solid Tumors
- Inflammatory Diseases: Gastrits, UC, CD
- Blood Cancer
- Cysts
- Polyps

Cancers

- MELANOMA
- BONE
- MYELOMA
- GLIOMA, SPINAL CORD
- PROSTATE, TESTIS
- HEAD and NECK
- OVARY ENDOMETRIUM CERVIX
- LUNG
- BLADDER
- BREAST
- STOMACH (GASTRIC), COLORECTAL
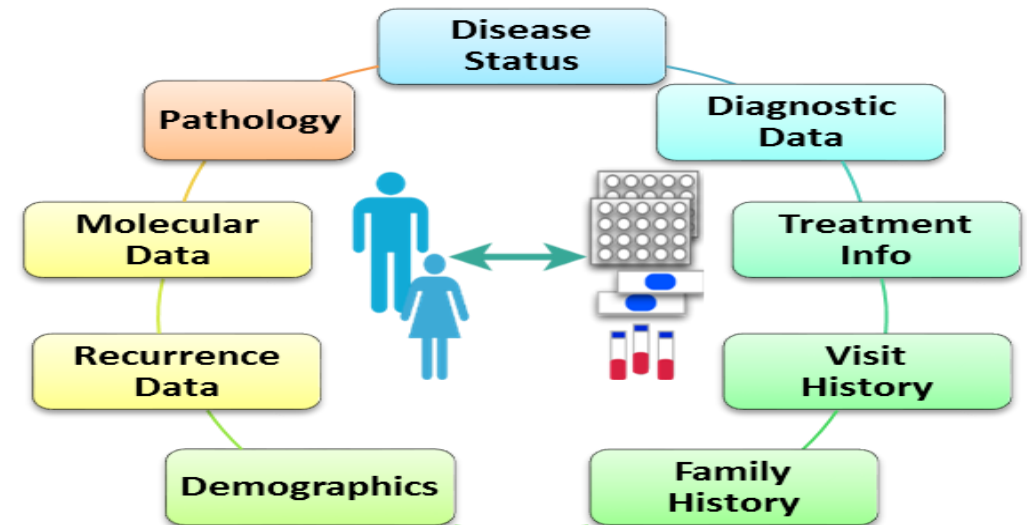
Samples and Data for >300,000 Patients, across All Diseases, (~50,000 being Cancer Cases), making Sapien one of the 10 largest biobanks in the world

Samples & Data are collected as per internationally accepted protocols with IRB approvals in place.
Samples used for NGS, IHC, FISH, whole slide Images for AI ML, Liquid biopsy, Cell Assays, FACS, ELISAs by Global pharma
(See testimonials slide 15)
Export process for Samples, Data, Images – all worked out

- Disease Status
- Pathology
- Diagnostic Data
- Molecular Data
- Treatment Info
- Recurrence Data
- Visit History
- Demographics
- Family History

Key Advantages of Sapien in 'omics

UK Biobank (UKB), and FinnGen (FG), are 2 large PPP consortia with 500K (~300K in FG) people's samples, longitudinal outcomes data (Phenotype data), combined with genomic data

Sapien is uniquely positioned to be __THE__ Asian partner with many advantages over UKB & FG

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UK Biobank, FinnGen

a) **Age range Limited**: 40-69 years

b) **Caucasian only**

c) **Low Diversity** : UK, Finland are both small, Island nations with low geographic, environmental, dietary diversity - homogenous population

d) **Heavily Pre-treated patients more common**
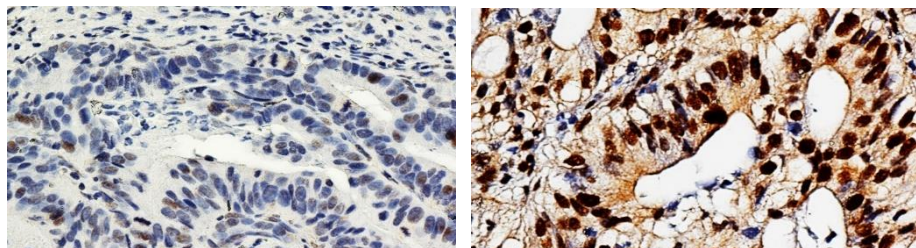
e) **Low volume** *of patients* : small populations

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Sapien biobank's Differentiators and Tremendous Potential

a) **Age range VERY HIGH** : Sapien samples span <1 month to 102 years

b) **Asian** : **Addresses the gap of <5% global 'omic data being from Asia / Africa**

c) **High diversity** : India is the 7th largest country, with varied climate, lifestyle, food & microbiome – heterogeneity needed available @ Sapien biobank

d) **Treatment-naïve patients common in India** : desirable for 'Omic studies

e) **High volume of patients**: India is the world's 2nd most populous country **(China doesn't allow samples to be exported so only Sapien can enable access to the largest population in the world),** with 72+ hospitals network

f) **Even Rare diseases** : Higher volume in India than elsewhere in the world due to sheer size of the population

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Predictus Biosciences — Precision Simplified

Ando K, Hamade Y et al. 2018. Developing a Phosphospecific IHC Assay as a Predictive Biomarker for Topoisomerase I Inhibitors.

Topoisomerase treatment response **predictive marker** in CRC

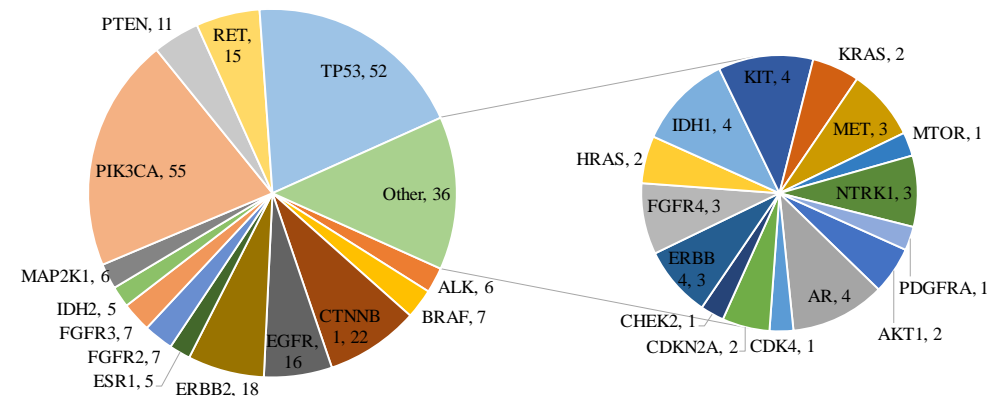Non-responder (left)   Responder (right)

OncoBloc™

ThermoFisher SCIENTIFIC

OncoMine NGS gene panel data using Sapien's Breast Cancer blocks: SNVs

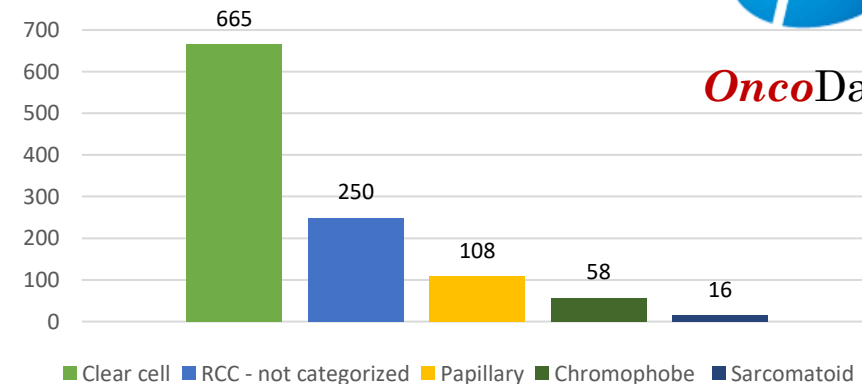**aveta⊙biomics**   **Onco**Prime™

Boston-based Botanicals drug company

"We approached Sapien because of their unique expertise and their library of patient-derived tumor tissues. Sapien's work is flawless and world-class and helped us get insights into the potencies of our drug candidates. Sapienbio's 2D and 3D models are exactly what we needed. The data that Sapien generated is part of our regulatory submission package."

Renal Cell Carcinoma - Histotype

Pfizer

OncoData

- Clear cell
- RCC - not categorized
- Papillary
- Chromophobe
- Sarcomatoid

Clear cell: 665, RCC - not categorized: 250, Papillary: 108, Chromophobe: 58, Sarcomatoid: 16

Real World Data on treatment choices of 1097 Renal Cancer cases, including 215 post-recurrence cases

Sapien Accesses High Volume of Patients, Pan-India, through 70+ Apollo Hospitals

Map of India showing Sapien/Apollo hospital locations: Delhi, Ahmedabad, Kolkata, Mumbai, Hyderabad - HQ (5 hospitals), Bhubaneswar, Vizag, Bangalore, Chennai : Cluster of 7 hospitals, including three dedicated to Cancer. Stars indicate Sapien Locations Coming Soon.

Number of Patients accessible to Sapien from 73 hospitals of Apollo

- Inpatient   :   10,250 beds
  470,000 patients/year

- Outpatient :   4.3 Million
  patients/year

All Formats and Variety of Samples Available:
FFPE blocks, flash-frozen tissue, normal controls matched plasma/serum, blood cells, live cells etc

Distribution of Diseases (in %) : Examples to showcase NCDs

ICD 10 Code	Diagnosis	Hosp 1	Hosp 2	Hosp 3
A	Infectious diseases	9	5	4
B	Infectious diseases	2	1	2
C	Cancer	9	27	4
D	Blood diseases including immune disorders	5	7	7
E	Endocrine, nutritional, metabolic diseases	20	18	33
F	Mental disorders	0	0	0
G	Nervous system	3	3	2
H	Eye, ear, mastoid diseases	6	2	2
I	Heart and circulatory	16	12	14
J	Respiratory	5	3	5
K	Digestive system	9	8	10
L	Skin and subcutaneous tissues	1	1	2
M	Musculoskeletal, orthopedics	7	4	9
N	Genitourinary, Kidney, Renal	7	9	6
	Others	0.6	0.3	0.3
	Total (in Percent)	100	100	100
	Average Yearly In-Patient Volume (approx)	**12000**	**20000**	**18000**

Patient Datasets Available to Sapien from our Partner Hospitals

1. Medical History : Partially available.

2. Visit diagnoses: ICD10 diagnosis code available up to 1 decimal point e.g., C50.9 for breast cancer

3. Medications: Usually available.

   Hospital Formulary List available for Indian brands for the most commonly used medications, stated in their generic form e.g., brand name Glivec (Gleevec in USA), generic name used in India is Imatinib which will be available

4. Procedures: Mostly available.

5. Demographics : Available. Typically includes vital signs, weight, height, BP (systole, diastole), age, gender.

6. Social history: Not commonly available.

   - Being collected manually for specific projects

7. Laboratory values: Mostly available.

8. Radiology : Summary of report usually available.

9. Treatment & Follow-up Data : Integrated from medical records and data sources, manually curated & coded

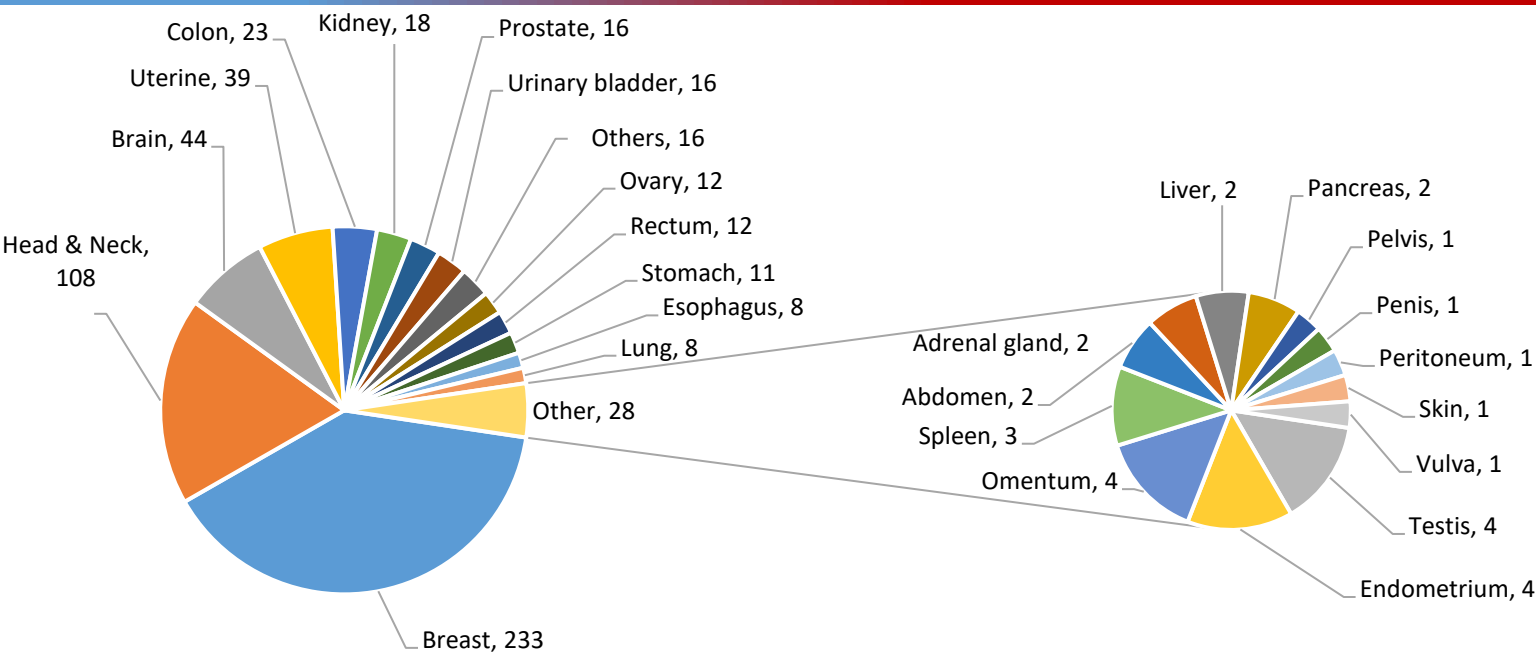# OncoBloc™ : Sapien's FFPE Block Inventory in Solid Cancers

INVENTORY OF SOLID CANCERS			
Disease	**Total**	**Biopsies**	**Resections**
Brain	1600	400	1200
Breast	5600	80	5520
Cervix	325	300	25
Colorectal	3500	1600	1900
Endometrial	490	140	360
Esophagus	270	225	45
Gastric	400	250	270
Head & Neck	3500	900	2600
Kidney	560	90	470
Liver	200	150	50
Lung	290	150	140
Lymphoma	900	750	150
Ovary	570	70	500
Pancreas	265	150	150
Prostate	2000	1200	1000
Thyroid	950	100	850
Urinary bladder	400	150	250
Uterine	200	120	80
Other cancers	>2500		

- >55000 cancer cases' samples available with demographic and diagnostic details

- Treatment and outcomes data available in breast, lung, CRC, renal, H&N cancers, can be added for other cancers

- Gene mutation data available for ~1200 cancer cases

- Adjacent Normal FFPE tissue available for most cancers except Brain - Tissues from *non-cancer* patients also available as normal control

- Matched sets of pre- and post-NACT blocks available.

- Matched sets of primary and metastatic tumor blocks available.

- IHC services available for commercial or client-provided antibodies

- High resolution digital images for digital pathology, ML, AI
  e.g., 1000 breast cancers with matched H&E ER,PR,Her2, Ki67
  ~600 different cancers with H&E, MSI by IHC

- Samples provided as blocks, unstained sections, H&E-stained slides, curls, DNA/RNA, or scanned slide images.

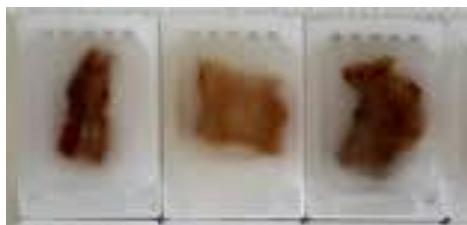# OncoBloc™ : Sapien's Flash Frozen Inventory in Cancers

Organ	No of cases	Percentage (>1%)
Breast	233	39.4
Head & Neck	108	18.2
Brain	44	7.4
Uterine	39	6.6
Colon	23	3.9
Kidney	18	3.0
Prostate	16	2.7
Urinary bladder	16	2.7
Others	16	2.7
Ovary	12	2.0
Rectum	12	2.0
Stomach	11	1.9
Esophagus	8	1.4
Lung	8	1.4

Organ	No of cases	Percentage (<1%)
Testis	4	0.7
Endometrium	4	0.7
Omentum	4	0.7
Spleen	3	0.5
Abdomen	2	0.3
Adrenal gland	2	0.3
Liver	2	0.3
Pancreas	2	0.3
Pelvis	1	0.2
Penis	1	0.2
Peritoneum	1	0.2
Skin	1	0.2
Vulva	1	0.2

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Sapien : Ideal Asian Genomics Partner

1. Sapien is prospectively collecting blood and tissue samples from solid cancers to enable large Genomics projects with consented Samples and Structured, Coded, Treatment and Outcomes data

2. Sapien can collect solid and hematological cancers – inclusion/exclusion criteria details to be shared by client

3. Deep learning possible with our Curated high quality samples & data

    • Matched tissue + Blood/ Plasma + Scanned Pathology slide images + Genomics data + Treatment & Outcomes data

Glass Slide   Digital Whole Slide

Real-Time Patient Data – IP + OP	
1	Demographics
2	Family history, smoking history etc
3	Diagnostic reports – Integrate Pathology, Mol Bio, Hematol, Radiology, outsourced markers
4	Scanned slides images
5	Surgery details, Discharge Summary
6	Stage and Grade
7	Treatment: Chemo, Radiation, Targeted, Palliative, co-meds
8	Response to Treatment – Lab reports, Radiology, Dx
9	5 year survival – DFS, OS
10	Recurrence, if any, and treatment for recurrence
11	Gene mutations and variations - Genomics

Sapien Polyglot Leadership Team – Internationally Experienced

Dr. Jugnu Jain – CEO, Co-Founder

- PhD - Cambridge UK, Post-doc - Dana Farber & Harvard Medical School
- 14 years Drug Discovery experience @ Vertex Pharmaceuticals, Boston
- Knows Pharma's need for translation and gaps therein very well
- 10 years' business experience commercializing Sapien with Global Companies

Dr. Soma Chatterjee – Director, Biobank & Ethics

- PhD – Chonnam Nat'l Univ, S Korea & Business Strategy – IIFT, India
- 20 years experience at Lonza and other companies, specifically sourcing and providing quality human samples ethically, to Global businesses
- Also Leads ethical compliance, Liaison with Govt agencies and IRBs, well-versed in government regulations

Dr. Rakesh Sharma – Scientist, Lab Assays

- PhD – Ruprecht-Karls-University & DKFZ, Germany
- 10+ years experience in cancer and immune biology
- Adept in patient tissue-based Primary cell establishment, including co-culture assays, FACS, ELISAs, Crispr-Cas9 gene editing, drug screening, target and biomarker studies
- Skilled in IF, confocal, live image microscopy and pathology techniques

Sapien: A Differentiated CRO

Multi-disease Biobank that combines personalized medicine products and drug discovery services for Pharma & Diagnostic companies

Many types of patient samples and data for <u>customized</u> genomics, molecular, cellular, pathology assays for validating drugs, drug targets and predictive biomarkers

Real World Evidence (RWE), data to support preclinical and clinical decision-making and patient stratification

Export process, complying with ethical guidelines is well-established.
Long-term partnerships with reputed global R&D Pharma / Biotech companies

Promoted by experienced scientist entrepreneurs with track record of international Pharma drug development and Global business experience

SAPIEN BIOSCIENCES

Thank you

Please contact us at :

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Meet in-person at BIO, 5-8th June 2023 at Boston

Vision and Mission

Sapien's Vision:

- A premier bioscience enterprise at the interface of healthcare and life sciences, with clinically relevant products, platforms and services, enabling the development of personalized drugs and diagnostics to improve patient lives.
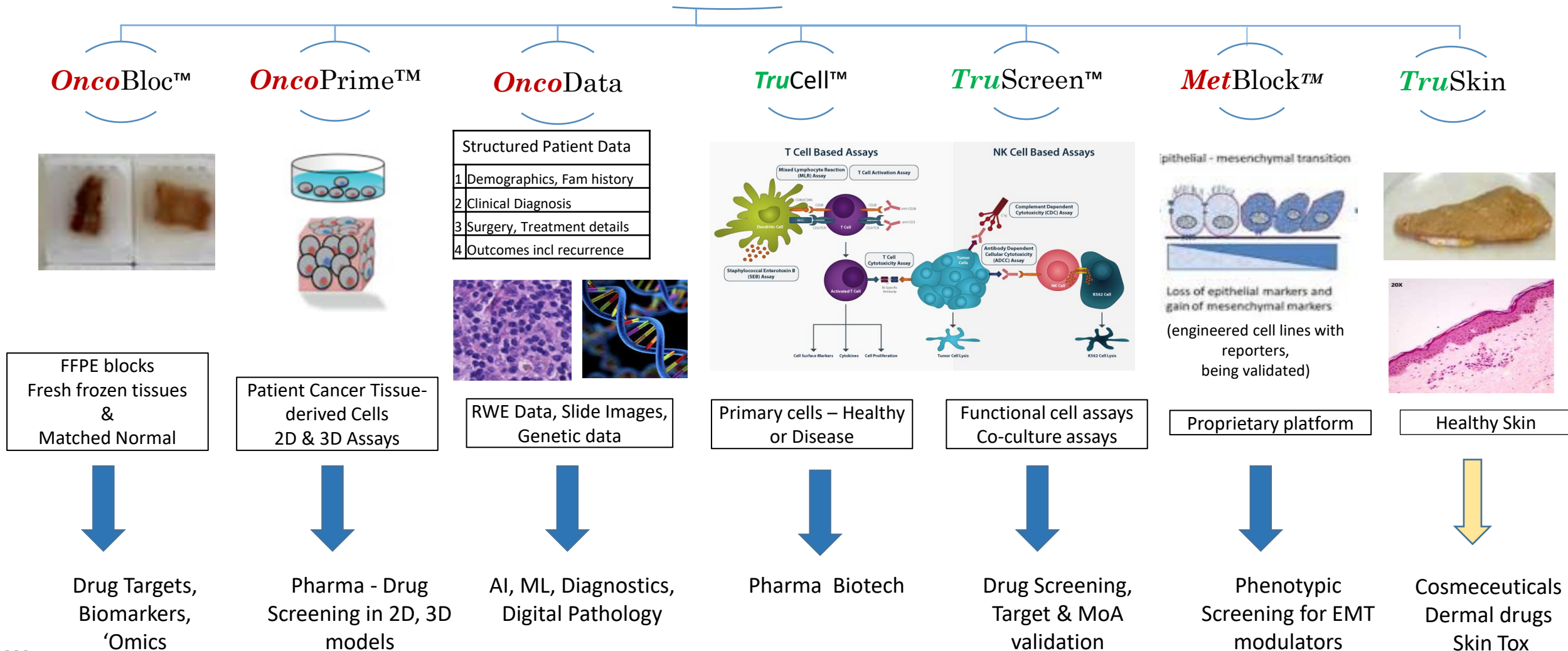
Sapien's Mission:

- Build a world-class biobank archiving ethically obtained, high quality patient samples and clinical data based in India.

- Harness biobank assets for the development of clinically important products with Pharma, Diagnostics, Genomics and Data Science partners.

- Mine longitudinal Outcomes data to optimize patient care at each stage - earlier detection, personalized treatment, monitoring of disease progression.
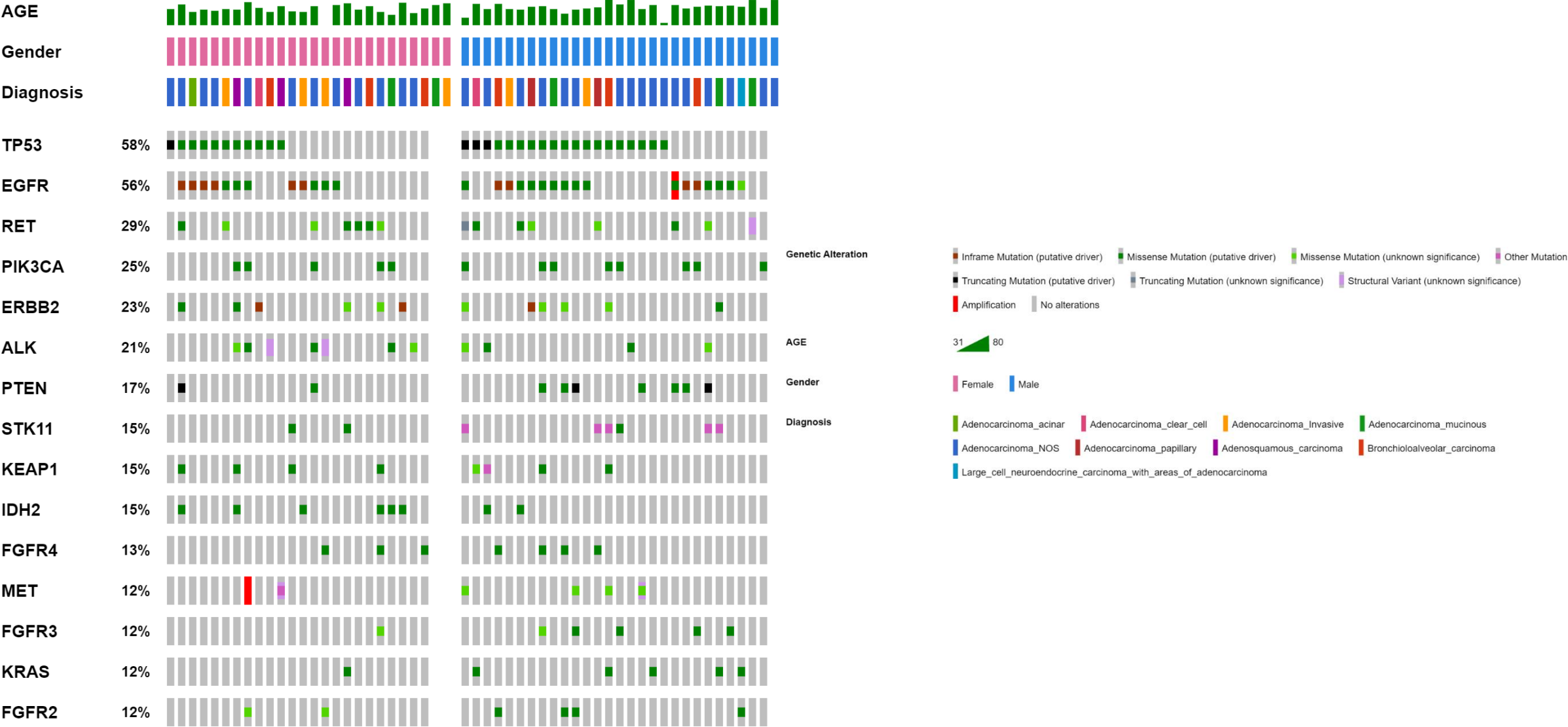
Sapien's Products & Services

R&D Platforms established using Patient as well as Healthy Human Samples and Associated Medical Data

OncoBloc™	**Onco**Prime™	**Onco**Data	**Tru**Cell™	**Tru**Screen™	**Met**Block™	**Tru**Skin

OncoData — Structured Patient Data

	Structured Patient Data
1	Demographics, Fam history
2	Clinical Diagnosis
3	Surgery, Treatment details
4	Outcomes incl recurrence

TruCell™

T Cell Based Assays — Mixed Lymphocyte Reaction (MLR) Assay, T Cell Activation Assay, T Cell Cytotoxicity Assay, Staphylococcal Enterotoxin B (SEB) Assay

NK Cell Based Assays — Complement Dependent Cytotoxicity (CDC) Assay, Antibody Dependent Cellular Cytotoxicity (ADCC) Assay

MetBlock™

epithelial – mesenchymal transition

Loss of epithelial markers and gain of mesenchymal markers

(engineered cell lines with reporters, being validated)

OncoBloc™: FFPE blocks Fresh frozen tissues & Matched Normal → Drug Targets, Biomarkers, 'Omics

OncoPrime™: Patient Cancer Tissue-derived Cells 2D & 3D Assays → Pharma - Drug Screening in 2D, 3D models

OncoData: RWE Data, Slide Images, Genetic data → AI, ML, Diagnostics, Digital Pathology

TruCell™: Primary cells – Healthy or Disease → Pharma Biotech

TruScreen™: Functional cell assays Co-culture assays → Drug Screening, Target & MoA validation

MetBlock™: Proprietary platform → Phenotypic Screening for EMT modulators

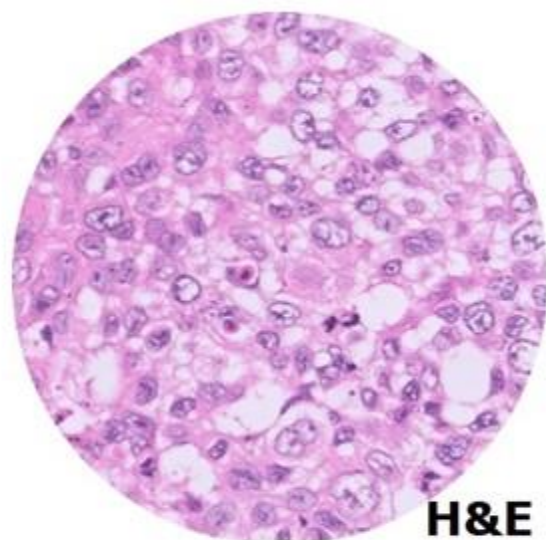**TruSkin:** Healthy Skin → Cosmeceuticals Dermal drugs Skin Tox
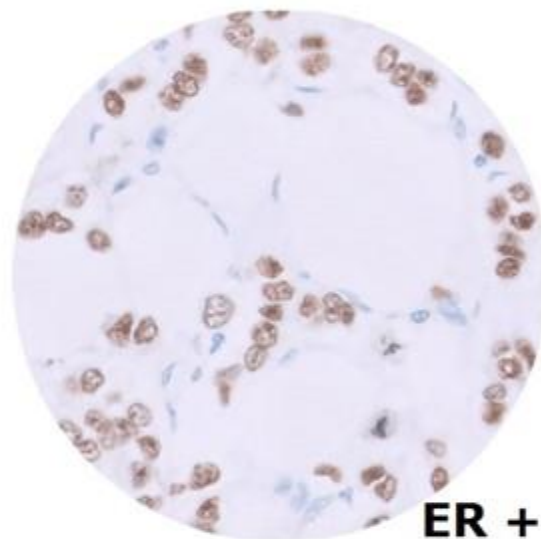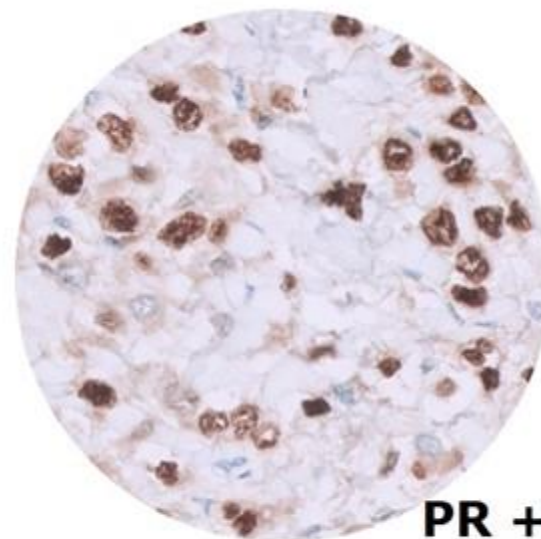
Lung Adenocarcinoma Data with ThermoFisher (n=55)

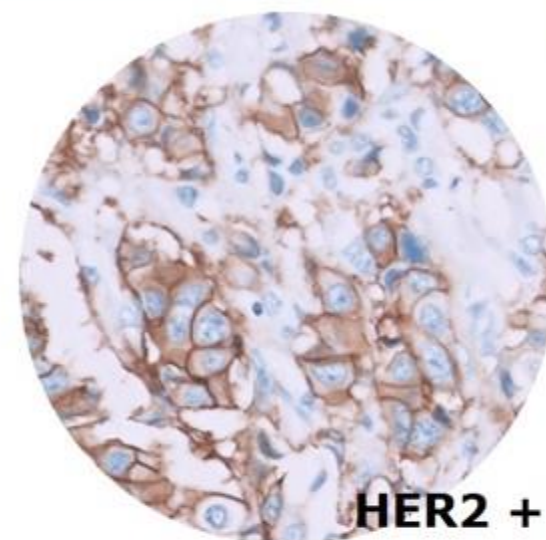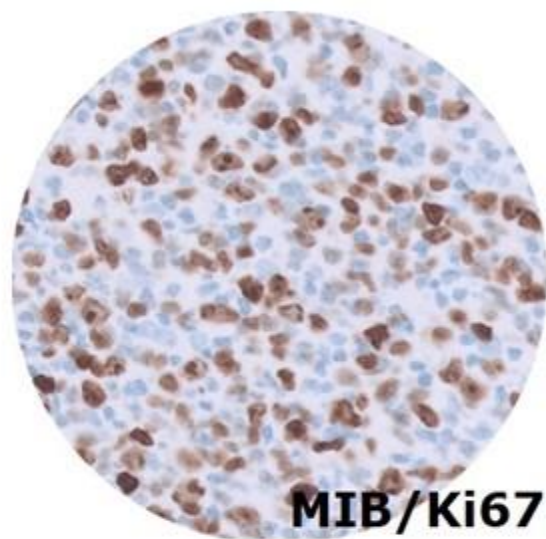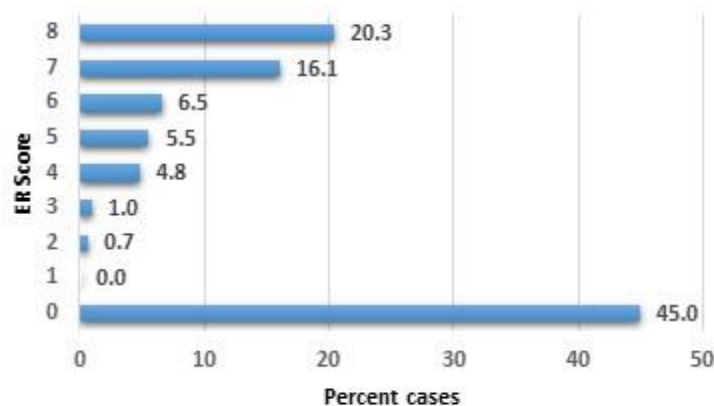# Matched Sets of Breast Cancer WSI : H&E, ER, PR, HER2, MIB / Ki67

H&E

ER +

PR +

HER2 +

MIB/Ki67

Distribution of ER Scores

ER Score	Percent cases
8	20.3
7	16.1
6	6.5
5	5.5
4	4.8
3	1.0
2	0.7
1	0.0
0	45.0

Distribution of HER2 scores

Her2 Score	Percent cases
3	40.8
2	8.4
1	4.0
0	46.8

1000+ cases of All Breast Cancer Subtypes, Non-malignant & Controls Available With Diagnosis in Sapien's Digital Slides Library