A black and white photograph of two hikers standing on a rocky mountain peak, seen from behind. They are holding hands and raising their arms in a celebratory gesture towards a bright, cloudy sky. The hiker on the left wears a plaid shirt and a backpack, while the hiker on the right wears a light-colored long-sleeved shirt and a backpack.

PERPETUAL CLINICAL TRIALS

Faster, more informative, best for the patient

Mika Newton, CEO

2019

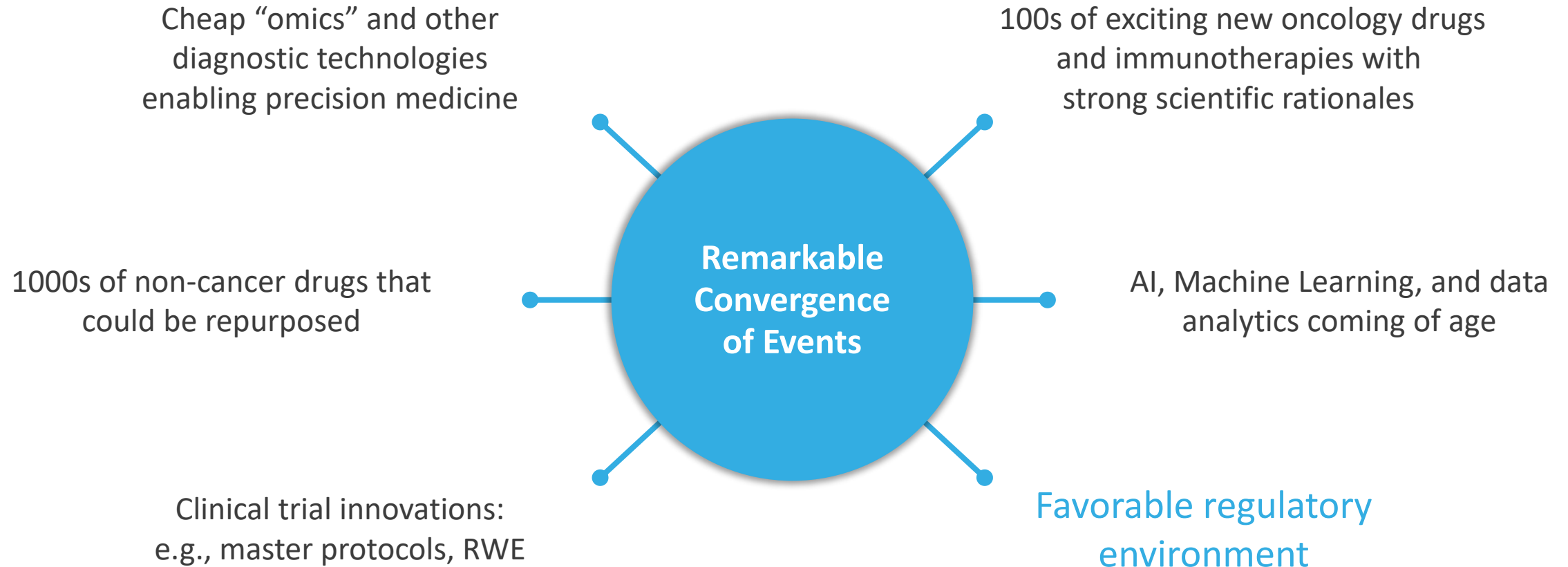
A background image of a patient in a hospital bed, seen from behind, looking out a window. The patient is wearing a patterned hospital gown. The room is brightly lit by natural light from the window. The text is overlaid on this image.

For Advanced Cancer Patients, Getting the Best Care Is a Nightmare

No one knows the optimal way to treat any cancer,
many patients **can't get or pay for** the drugs and technologies
they need
and treatment **outcomes vary** widely

Each year thousands die unnecessarily

But we live in a very exciting time



Traditional Development Is In Trouble

CLINICAL TRIALS ARE UNSUSTAINABLE

Too slow (5-10 years)

Too expensive (\$100M+)

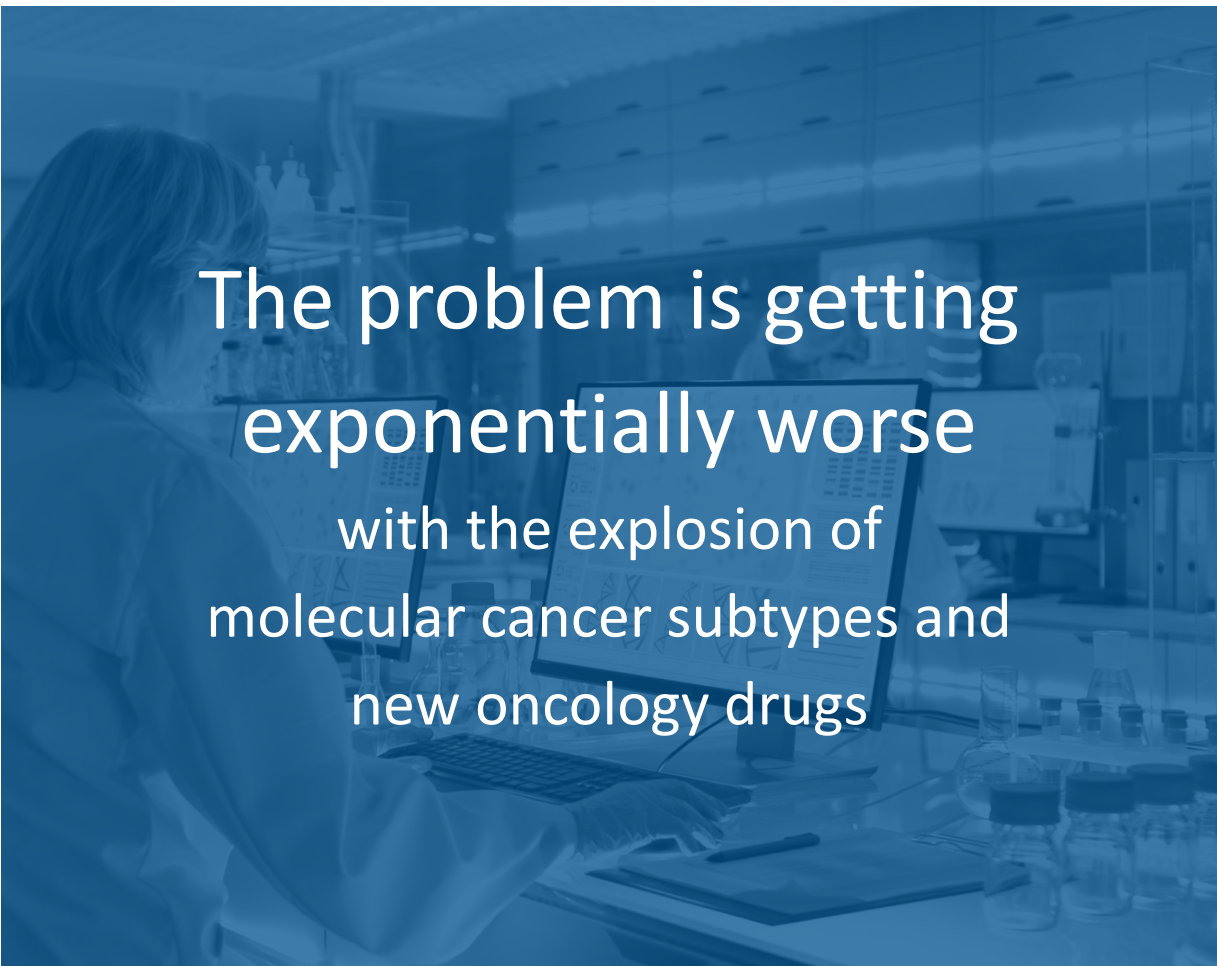
Only 5% of patients can, or do participate

TOO MANY OPTIONS, TOO FEW PATIENTS

~3500 open IO trials in the US

Requiring ~600,000 patients

Only ~50,000 patients / year enroll in trials



The problem is getting
exponentially worse
with the explosion of
molecular cancer subtypes and
new oncology drugs

Regulators Agree That Change Is Needed

“We must bridge clinical research and health care or the entire enterprise is going to fall down.” Janet Woodcock, Director, CDER. FDA

- Master protocols
- Adaptive designs
- Seamless trials
- Expanded access
- Real-world evidence (RWE)

Helpful but not enough to solve the existential problem: too many options, too few patients

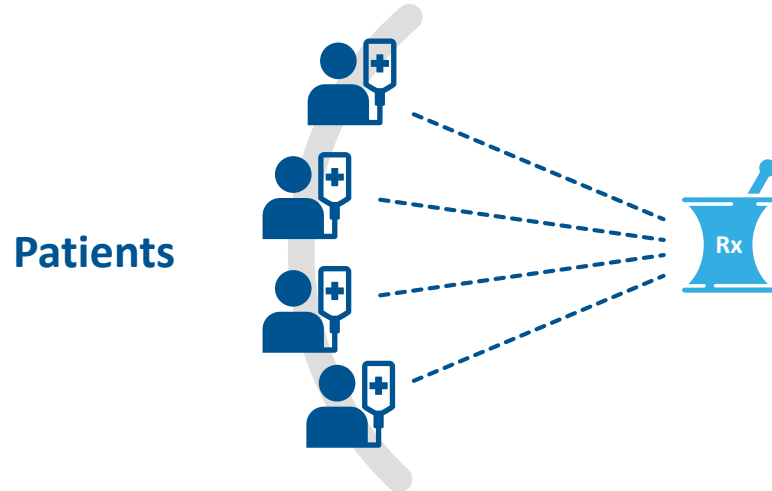


We need a
paradigm shift
to integrate clinical research
and care

From Approving Products to Curing Patients

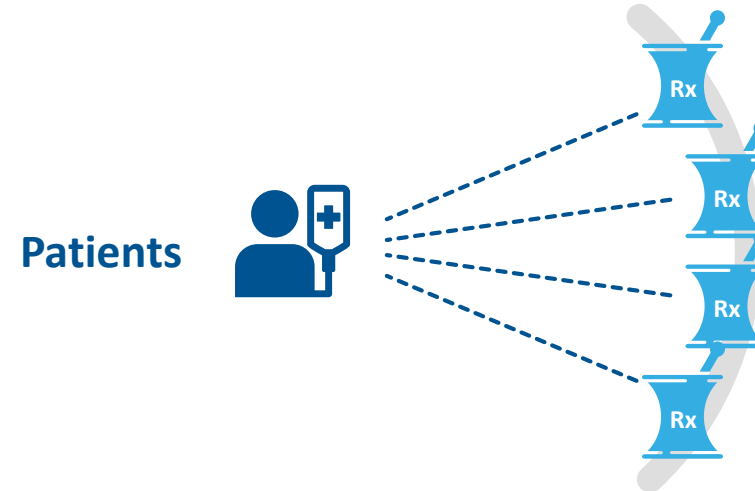
OLD WAY

Trials finding best patients
for a given therapy



XCURES

Leveraging knowledge and AI to find the
best treatment regimens for each patient



xCures Platform:

An AI-supported **precision oncology platform** that finds and recommends novel treatment options, facilitates access, informs decision-making, and records outcomes.

A **perpetual trial** that slashes site setup times and that continuously learns from *all* patients, *all* physicians, *all* therapies, *all* diagnostics, *all* the time.

Creating value

- Faster, cheaper development of drugs and diagnostics
- Payers pay only for what works
- Patients get access to the most promising treatments



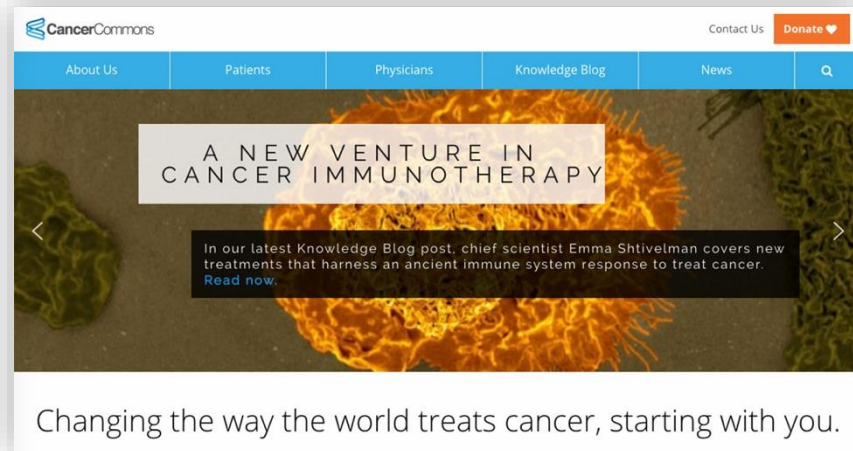
ARIANNA

Patient with DIPG holding her investigational drug she got access to with xCures

We Have Partnered with Trusted Cancer Networks to Bring Patients and Oncology Experts into Our System



RESPECTED NON-PROFIT



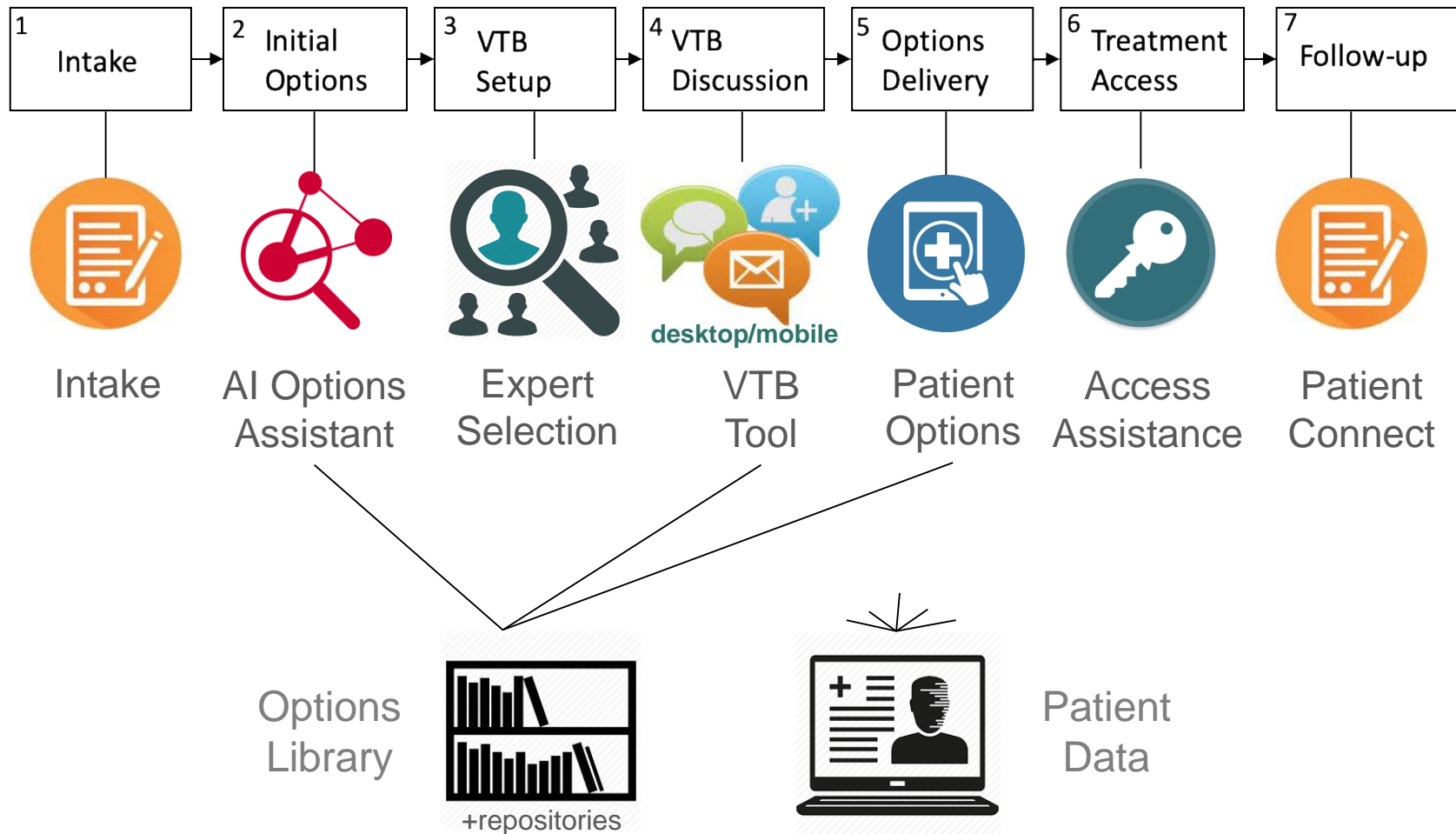
- Network of world-class physicians and researchers
- 4,000+ patients who have benefitted from virtual tumor boards
- Multiple peer reviewed publications
- American Cancer Society collaborator



Software and Services

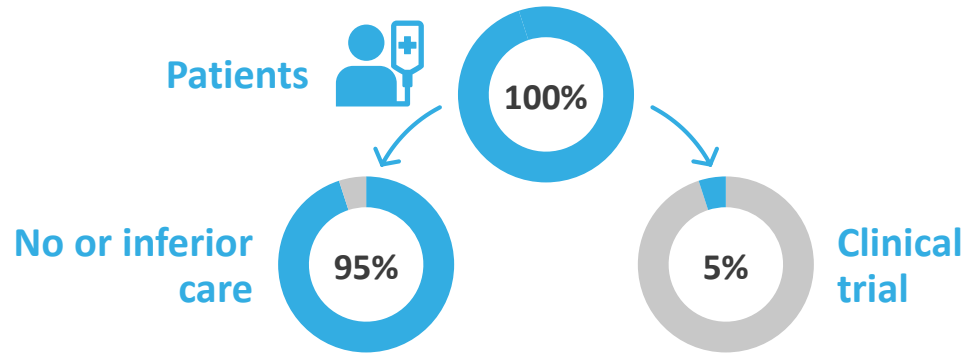
- **Treatment options** from virtual tumor boards, past cases, outcomes data
- **Access to drugs** needed to act on those recommendations
- Capture resulting **real-world data**
- **Coordinate** options across patients to optimize outcomes and learning

Applications / Systems



Slashing the Time and Cost of Development

TRADITIONAL TRIALS

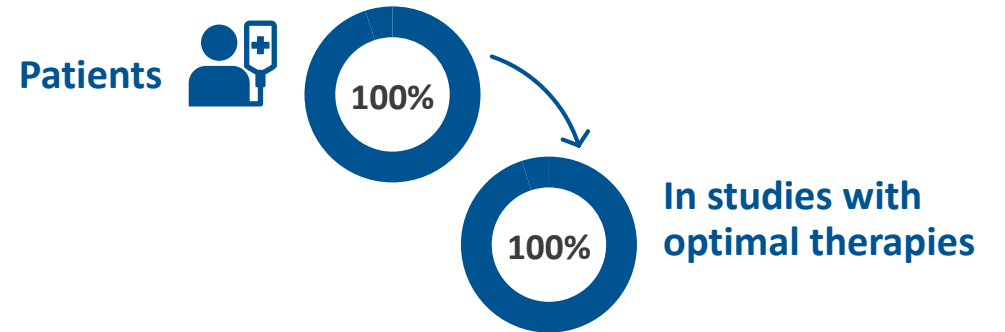


- Inclusion/exclusion criteria
- Randomized control
- Geographic disparity

5-10 years, 200 patients @ \$50,000

**Each site / phase starts anew
New sites take months**

XCURES TRIALS

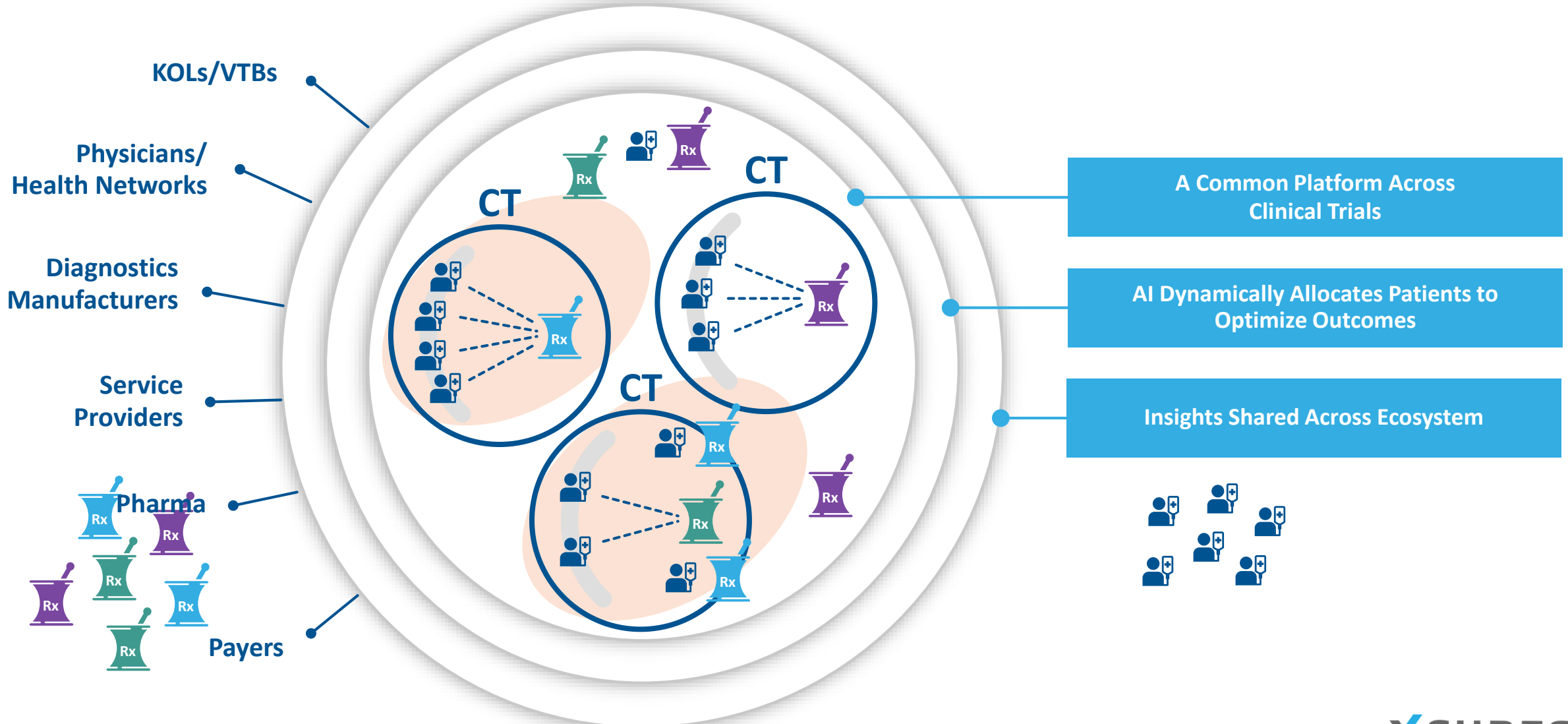


- No inclusion/exclusion
- No randomized control
- All geographies

1 year, 20 patients @ \$2,000

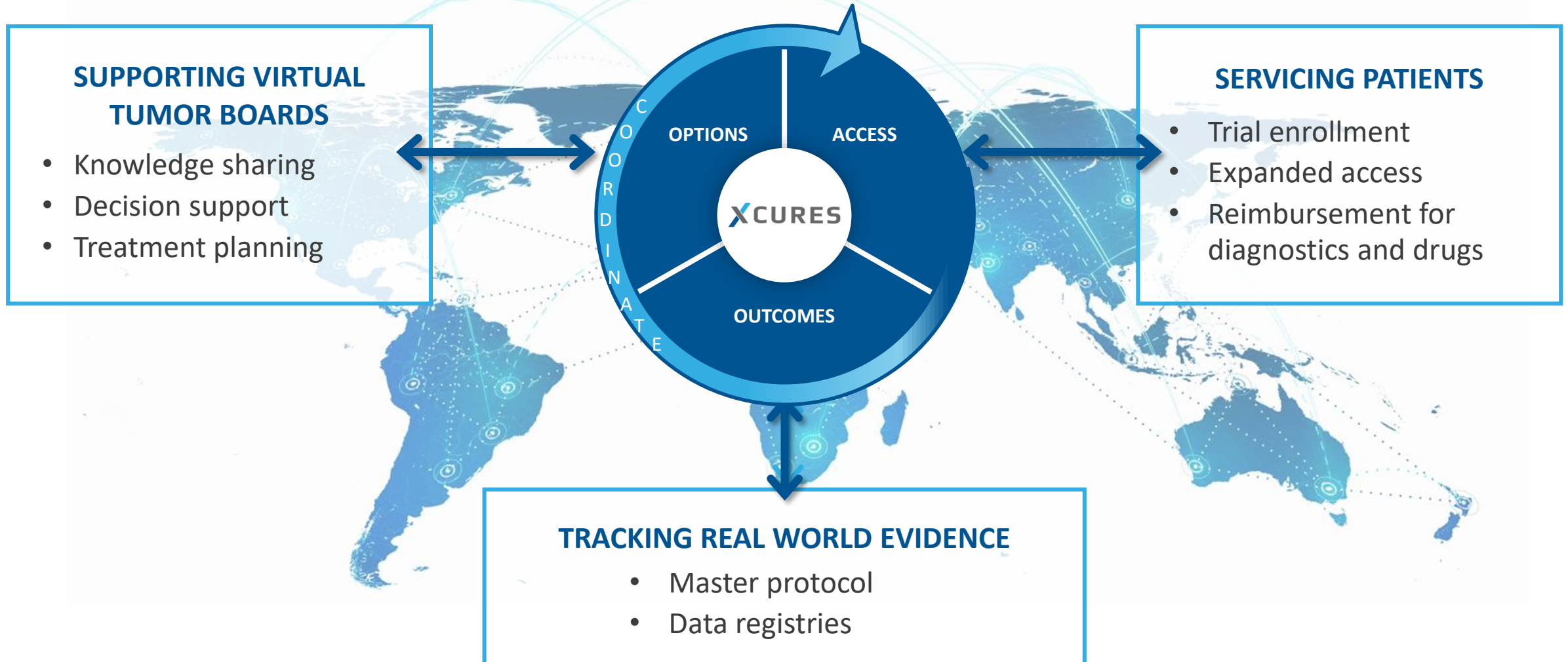
**Always on and siteless
Costs amortized across
all therapies and diagnostics**

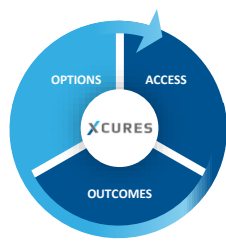
Creating Value Through a Master Platform and AI



xCures Platform: Options, Access and Outcomes

LEARNING FROM ALL PATIENTS. ALL PHYSICIANS. ALL THERAPIES. ALL DIAGNOSTICS. ALL THE TIME.





Options – Using Experts and AI to Optimize Care



Knowledge Sharing

NLP to capture treatment options, recommendations, and rationales from literature, conferences, social media, and real-world evidence



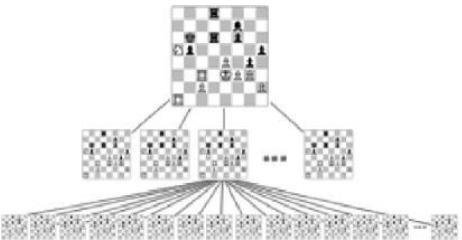
Decision Support

Virtual Tumor Boards develop treatment options for each patient, balancing personal insights against outcomes data and new options injected by researchers and industry.

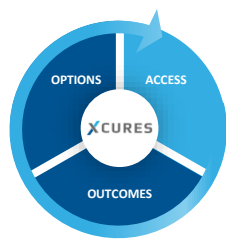


Treatment Planning

Evaluating patient’s treatment longitudinally with multiple drug regimens, to maximize shots on goal



Source: stanford.edu



Access – Getting the Right Care to Patients

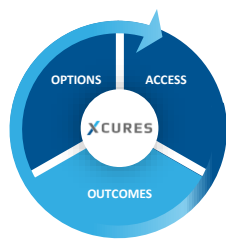
xCures SERVICES

- Trial matching and enrollment (ethical)
- Manage expanded access programs and trials
- Pay-for-performance program
- Clearinghouse for EA and off-label therapies
- Real world data gathering of impact of diagnostics use in decision making



BENEFITS

- Patients get access to the latest technologies
- xCures gets hot drugs on our platform for use by patients in Perpetual Trials
- Companies get real world data to accelerate approvals, label extensions, reimbursements
- Physicians get administrative support



Outcomes – Generating Real World Evidence

XCELSIOR Study

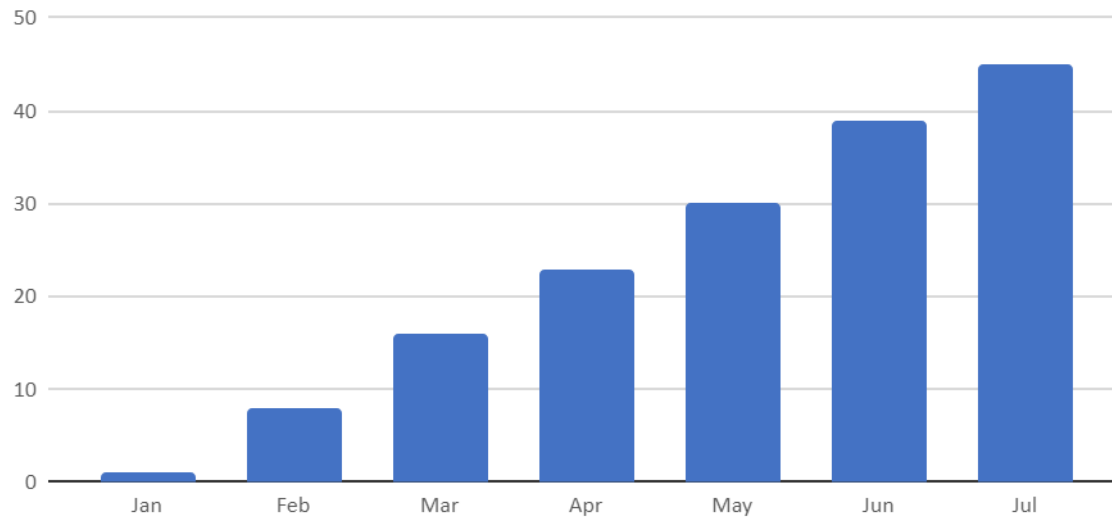
- IRB-approved Master Protocol
- Always-on: All patients and all treatments
- Add new sites, PIs, and drugs in days through amendments, sub-PIs, and subprotocols
- Patient-centric design: minimal inclusion / exclusion criteria; no randomized controls
- Level 1: Observational registry captures longitudinal, regulatory grade, treatment and outcomes data
- Level 2: Virtual Tumor boards and Virtual Trials seek to optimize individual outcomes and collective learning
- Innovative statistics for efficient signal generation from small data sets



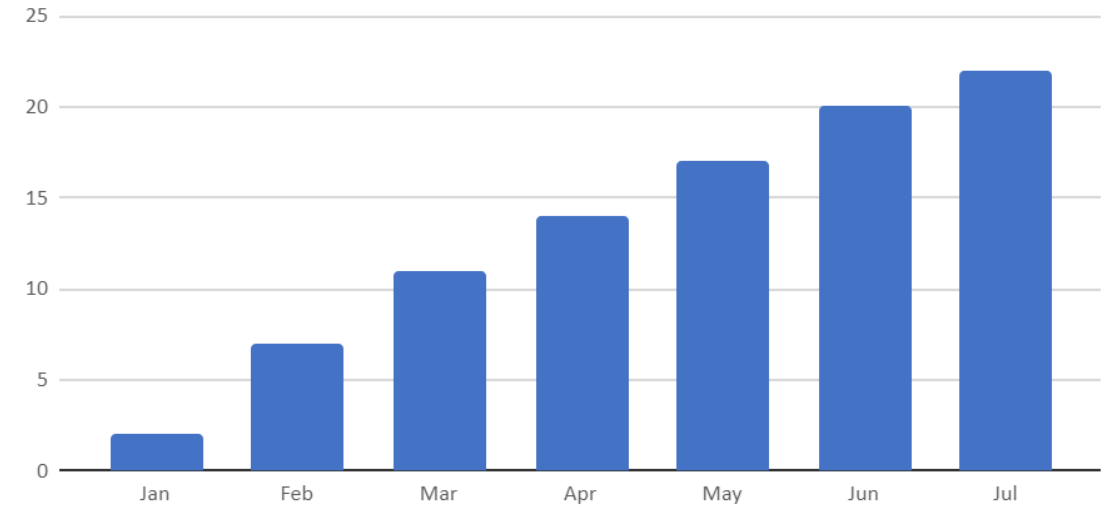
- 21 CFR Part 11 Validated, HIPAA & FISMA compliant, and WHODrug and MedDRA certified EDC system
- All access and activity in the system is tracked
- Audit trail shows who made a change, the date and time, and the old and new values
- Standardized data reporting forms support precision oncology studies for most solid tumors
- Reporting forms can be quickly customized to capture study-specific fields

Pilot with Expanded Access to ONC201 Shows Patient Interest

ONC201 EAP Total Patients Approved



ONC201 Sites Activated

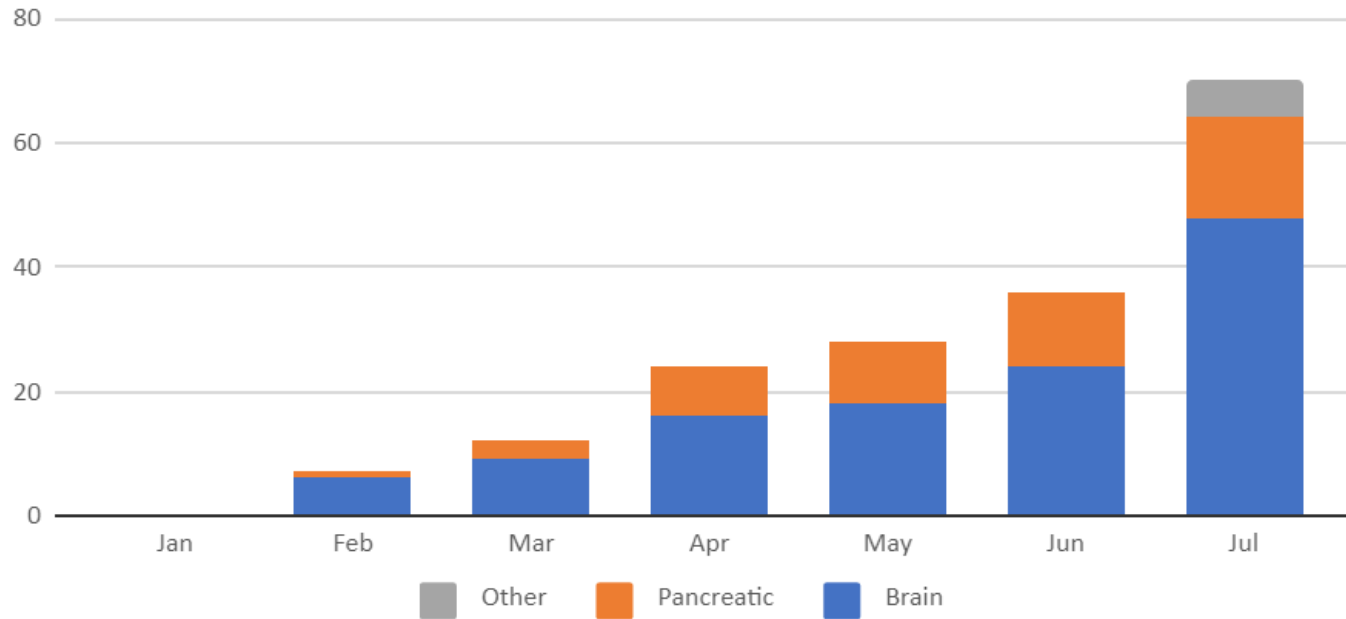


<u>ONC201 EAP Patients</u>	Jan	Feb	Mar	Apr	May	Jun	Jul
Total Patients Approved	1	8	16	23	30	39	45
<u>ONC201 Sites</u>	Jan	Feb	Mar	Apr	May	Jun	Jul
Sites Activated	2	7	11	14	17	20	22

- Average Site Activation Time – 28 days
- Protocol was expanded in June
- Demand from EU strong evaluating expansion

XCELSIOR – A Patient-Centric Platform Trial for Precision Oncology

XCELSIOR Patient Enrollment



- Platform release in early July resulting in accelerated enrollment
- Initial focus has been on Pancreatic and Brain cancer but starting to accrue other cancer types

XCELSIOR Patient Enrollment	Jan	Feb	Mar	Apr	May	Jun	Jul
Brain	0	6	9	16	18	24	48
Pancreatic	0	1	3	8	10	12	16
Other	0	0	0	0	0	0	6
Total	0	7	12	24	28	36	70

Initial results are promising

A Swedish patient spent significant resources to get assessed for the ONC201 pediatric glioma trial. He was not eligible.

We were able to get him onto the ONC201 expanded access protocol.

After 4 months of ONC201 use, the tumor has shown a decrease of 20 % on the latest MRI

We continue to monitor the outcomes and use the data for future decision making





PERPETUAL CLINICAL TRIAL
Faster, more informative, best for the patient

[XCURES.COM](https://xcures.com)

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