Tanner Pharma GROUP

COMPANY OVERVIEW

BIO-INTERNATIONAL
SAN DIEGO 2022

OUR CORE PURPOSE

Improving Lives by Increasing Access to Medicines Around the World

OUR MISSION

Relentlessly pursue and deliver innovative solutions that support patients in need

OUR APPROACH

Build collaborative partnerships with those that share in our vision of providing access to medicines across the globe

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Recognizing an Unmet Need

2001

Bourne Partners

Banks Bourne founded Bourne Partners, a healthcare-focused merchant bank and the parent company of Tanner Pharma Group

BOURNE PARTNERS

2002

TannerLAC

Company is formed to commercialize medicines in non-core markets, particularly Latin America

2005

TannerGAP

Tanner Pharmaceuticals is formed to resolve unmet medical needs via Named Patient Supply channels

2015

TannerCTS

UK office opened to support launch of clinical trial services, including sourcing of comparators and RLDs

2016

Non-Profit

Launch of partnership with The Max Foundation and donation programs with Pfizer, BMS, Novartis, Incyte and Takeda

The Max Foundation

2017

TannerMAP

Swiss office opened to support launch of global Managed Access Programs division

2019

TannerCares

Rare Disease

Tanner joins Global Genes and PQMD, to share its expertise and improve patient outcomes globally

Global Genes® Allies in Rare Disease

PQMD

2020

Global Impact: COVID Response

Supplier of COVID-19 lateral flow test kits to UK Government

Significant scale-up of distribution capabilities to manage massive volumes of medical supplies

2021

Global Expansion

Growth of CTS Services

Continued response to global COVID needs

Global Alliance for Rare Disease (GARD) member

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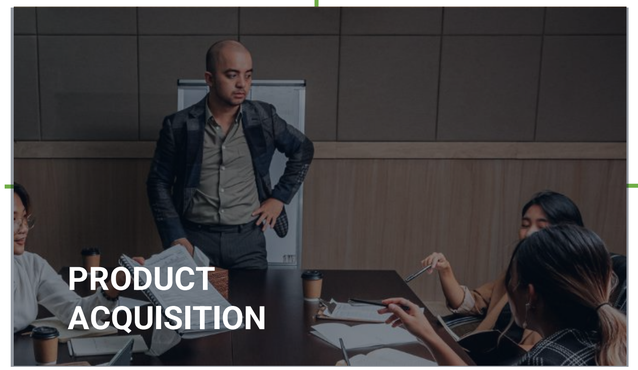
TannerLAC

OUR EXPERTISE

Promoting Licensed Medicines with a Focus on Latin America



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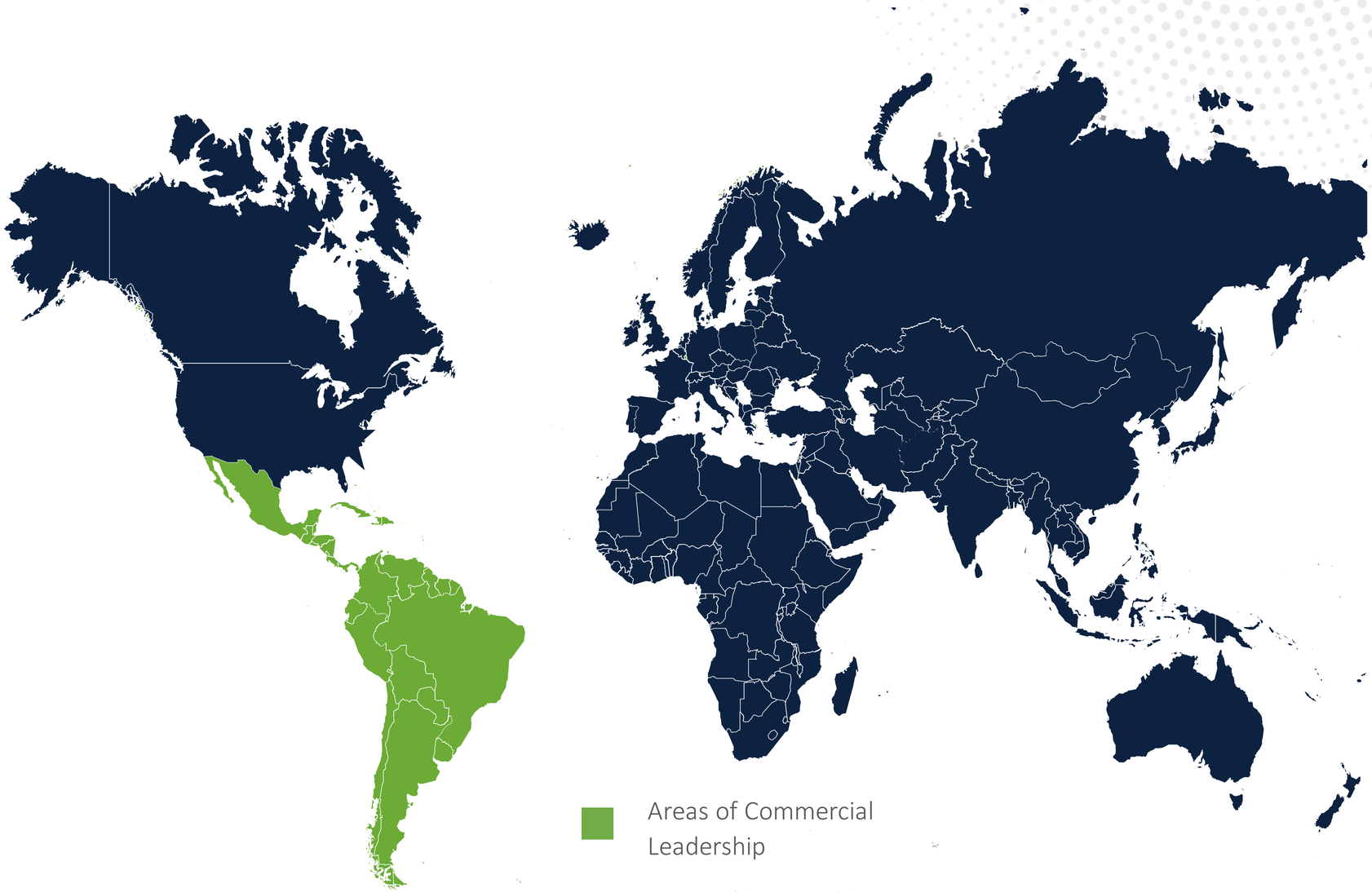
LICENSING, ACQUISITION & COMMERCIALIZATION

About TannerLAC

The History

The LAC division licenses, registers, promotes and commercializes specialty pharmaceutical products in emerging markets.

Over 20-year history serving as a single-partner which delivers access to emerging markets while minimizing risk, investment and resources of the product owner.



LICENSING, ACQUISITION & COMMERCIALIZATION

TannerLAC Process

New product opportunity

Product cost supplied by product owner

LAC becomes exclusive license holder for product transfer or first-time registration

LAC trains local partner's sales force and creates marketing launch plan

Product launched and promotion begins

Product assessment

Deep product analysis

LAC choses best local partner for distribution and to joint preparation of marketing approval submission

LAC becomes the single point of contact for all operations

LICENSING, ACQUISITION & COMMERCIALIZATION

TannerLAC Capabilities

TURNKEY SOLUTIONS

Single-partner solution for launching and/or promoting a new or acquired product in emerging markets

FLEXIBLE PARTNERSHIP STRUCTURES

Tailored agreements that meet your needs, whether through licensing, acquisition or fee-for-service arrangements

REGULATORY & LEGAL EXPERTISE

Deep technical knowledge and experience with local regulations for product registration

LOCAL RELATIONSHIPS

Long-standing relationships with regulatory agencies, KOLs, and local stakeholders

WORLD-CLASS

Market-specific distribution, promotion and sales strategies

TannerLAC

LICENSING, ACQUISITION & COMMERCIALIZATION

Therapeutic Areas of Experience

Gastroenterology

Ophthalmology

Urology

OB-GYN

Orthopedics

Respiratory

Hematology

Oncology & High Specialty

CNS

Cardiology

Specialty Antibiotics & Antifungals

Hospital Products

Metabolic Hormone Products

Diagnostics & Medical Devices

Critical Care

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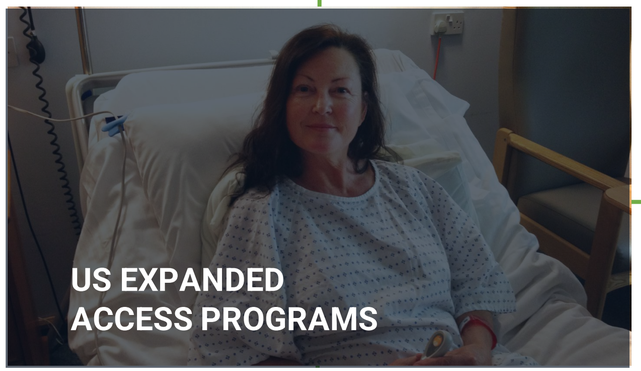
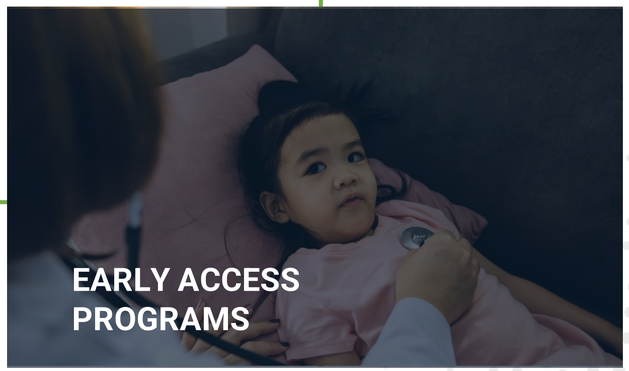
TANNER MAP

Supplying Patients in Markets Where a Medicine is Not Commercially Available





Motivation for Early Access Programs

Provide patients with no alternatives access to potentially life-improving or life-saving **treatment**

Collection of **real world evidence** and collection of safety data

Provide **continued access** to treatment after clinical trial

Pre-launch **physician and payor experience**

Greater product awareness, possibly driving higher sales at launch

Generate **revenue** to offset costs of development

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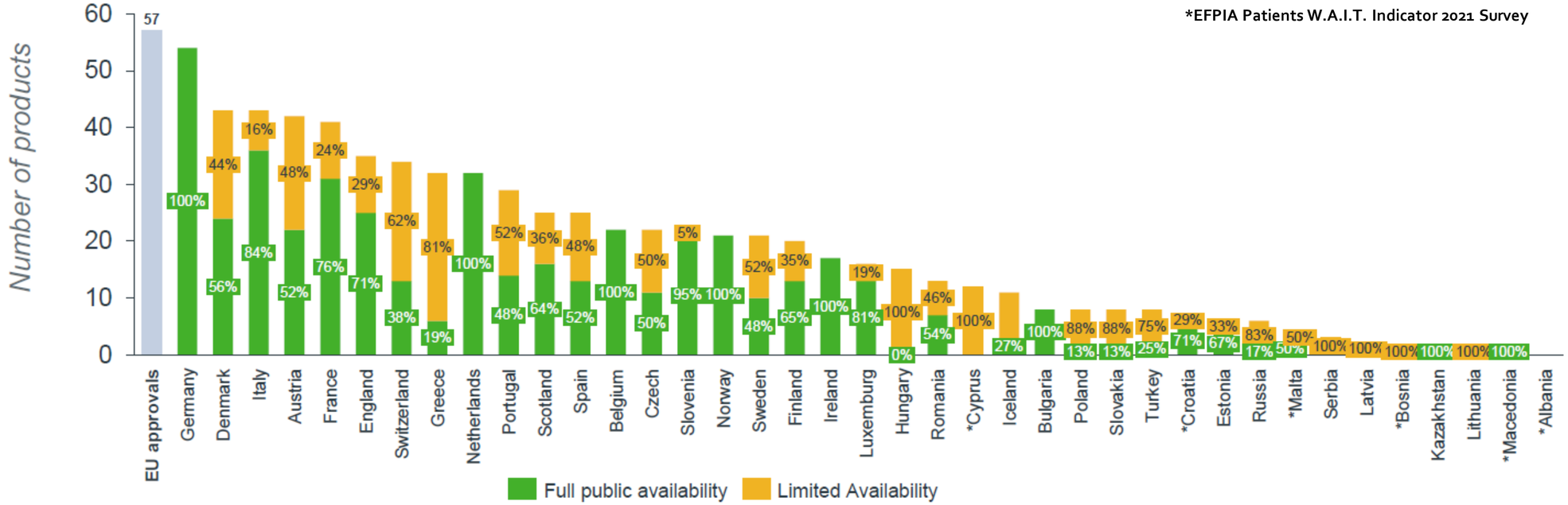
Orphan rate of full availability (2017-2020)*

The **rate of full availability** is a new indicator which shows the proportion of medicines available to patients in European countries as of 1st January 2022 (for most countries this is the point at which the product gains access to the reimbursement list†) without any restrictions to the patient population, or through named patient basis schemes which have increased significantly in recent years and were not always captured in survey submissions.

*EFPIA Patients W.A.I.T. Indicator 2021 Survey



European Union average: 21 products available (37%), limited availability (45% of available products). Ireland, Norway and Netherlands did not submit complete information on restrictions to available medicines meaning LA* is not captured in these countries. †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.

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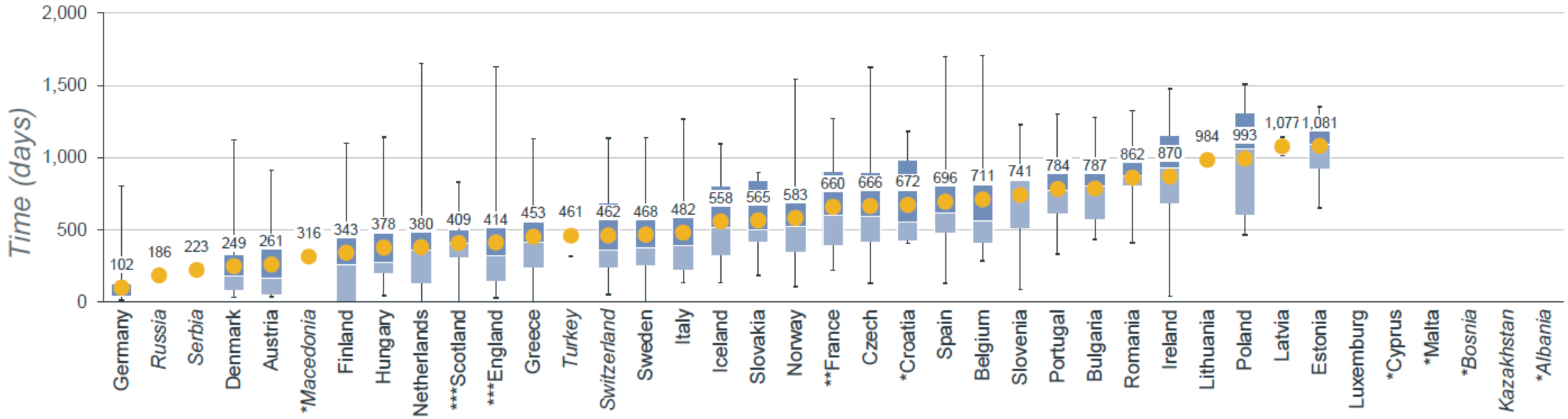
Orphan time to availability (2017-2020)*

The **time to availability** is the days between marketing authorisation and the date of availability to patients in European countries (for most this is the point at which products gain access to the reimbursement list†). The marketing authorisation date is the date of central EU authorisation in most countries, except for countries shown in italics where local authorisation dates have been used. Data is correct to 1st January 2022.

*EFPIA Patients W.A.I.T. Indicator 2021 Survey



	Germany	*Russia*	*Serbia*	Denmark	Austria	**Macedonia*	Finland	Hungary	Netherlands	***Scotland	***England	Greece	*Turkey*	*Switzerland*	Sweden	Italy	Iceland	Slovakia	Norway	**France
Available medicines / 57	54	6	3	43	42	1	20	15	32	25	35	32	8	34	21	43	11	8	21	41
Dates submitted / 57	54	1	1	42	42	1	20	15	32	25	35	19	2	13	21	43	11	8	21	31

	Czech	*Croatia	Spain	Belgium	Slovenia	Portugal	Bulgaria	Romania	Ireland	Lithuania	Poland	Latvia	Estonia	Luxemburg	*Cyprus	*Malta	**Bosnia*	*Kazakhstan*	**Albania*
Available medicines / 57	22	7	25	22	22	29	8	13	17	1	8	2	6	16	12	4	1	1	0
Dates submitted / 57	22	5	25	22	22	14	8	12	17	1	8	2	6	0	0	0	0	0	0

European Union average: 636 days (mean) †In most countries availability equates to granting of access to the reimbursement list, except in DK, FI, NO, SE some hospital products are not covered by the general reimbursement scheme. *Countries with asterisks did not complete a full dataset and therefore availability may be unrepresentative.; **In France, some innovative products without competitors can be made available prior to market authorisation under the system of Temporary Authorisations. As these are not taken into account in the analysis, the average would be lower. ***In the UK, MHRA's Early Access to Medicines Scheme provides access prior to marketing authorisation but is not included within this analysis, and would reduce the overall days for a small subset of medicines.

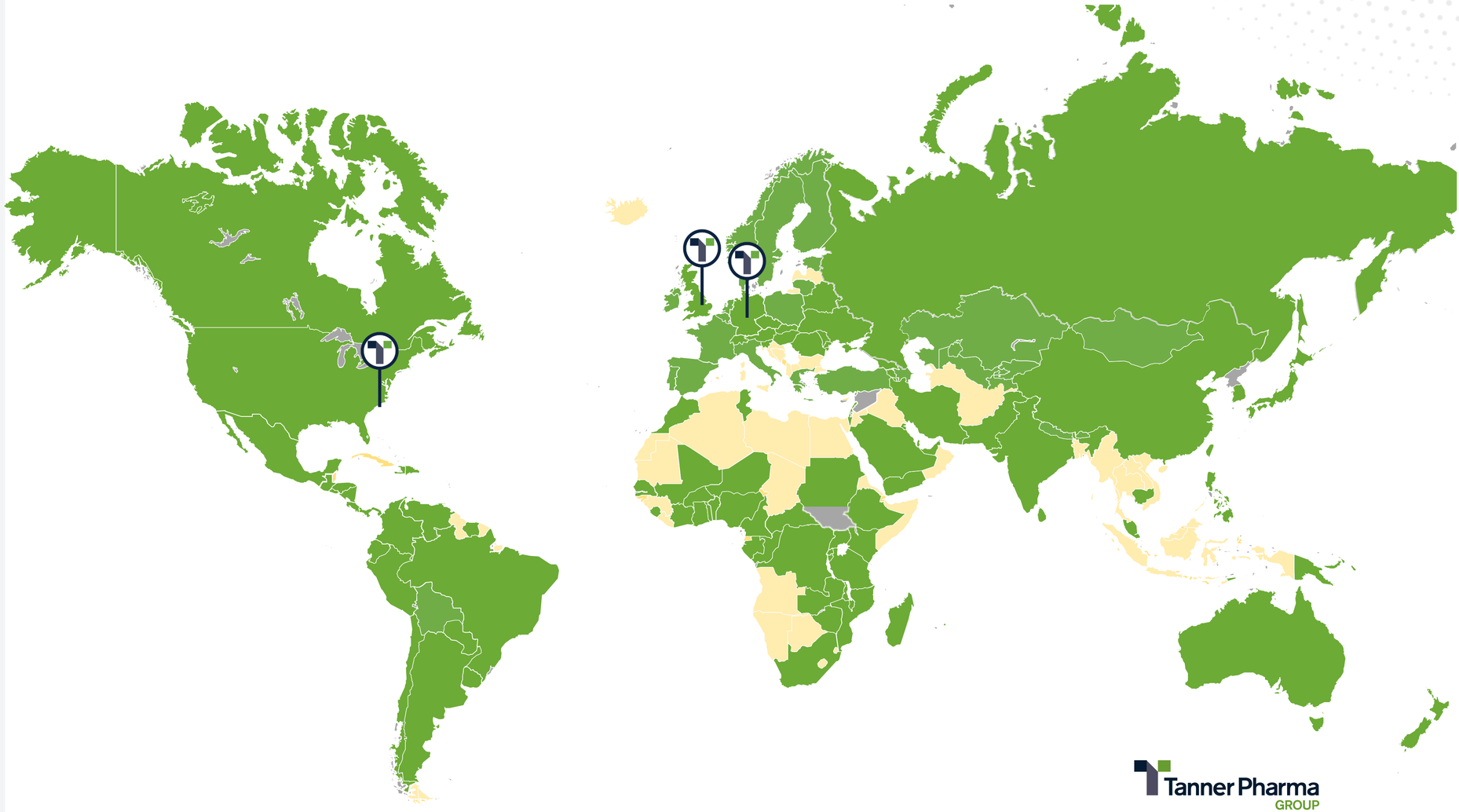
Our Global Reach

Tanner Warehouse Network

United States
Germany
United Kingdom

In-Country Services

Direct Shipments



USA Expanded Access Programs



	Single Patient IND	Intermediate Size	Treatment Protocol
Number of Patients	Single Patient	Up to 100 Patients	Above 100 Patients
Sponsor	Physician	Physician, Manufacturer, or 3rd Party	Physician, Manufacturer, or 3rd Party
Criteria	▪ Physician must determine that the probable risk from the medicine does not outweigh that from the disease ▪ FDA must determine that the patient cannot obtain access under another type of IND or protocol ▪ FDA requires written summary report, and may require special monitoring if use is for an extended duration	Needed in the following situations: ▪ Medicine being developed but patients requesting the medicine are unable to participate in the trial ▪ Medicine not being developed, for example because the disease is so rare that the sponsor is unable to recruit patients for a clinical trial ▪ Approved medicine no longer marketed or unavailable due to shortage	▪ Medicine is being investigated in clinical trial designed to support marketing, or trials are complete ▪ Company is actively pursuing marketing approval ▪ Sufficient evidence of safety and effectiveness with evidence from phase 3 or compelling data from phase 2 clinical trials
Emergency Access Allowed	Yes	No	No

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What is a Named Patient Program (NPP)?

Definition of Named Patient Supply

- A physician-driven regulatory pathway enabling pre-approval access in certain regions where a medicine is not available commercially
- Can be provided free-of-charge or on a chargeable basis
- Often companies will create a Named Patient Program (NPP) to provide physician education, ensure that patients are enrolled in line with the approved indication, and capture of additional clinical data, as allowed
- Today, an NPP is a standard part of a company's global market access strategy

NPP Requirements

- ✓ **Legislation to provide access to medicines through named patient supply outside the US varies from country to country**
- ✓ Legislation broadly states companies are permitted to respond to unsolicited requests for a medicine that is not available commercially in that country and requires that a physician obtain permission from their local competent authority to treat a specific or "named" patient under their care as long as therapeutic alternatives are not available.
- ✓ Once that approval has been granted, the medicine can be imported by the physician on behalf of a specific or named patient
- ✓ Typically, it is required that there is at least one global approval (e.g. FDA, EMA, CFDA) before a medicine can be supplied on a chargeable basis

CASE STUDY

Early Access to Support EU Market Access Strategy

Situation

Pharma Company's medicine for an ultra-rare liver disease was approved by FDA and EMA and was beginning launches in Europe. The company wanted to achieve a broad uptake at commercial launch and wanted to use early access to give more KOLs experience with the medicine and to maximize the number of patients taking the medicine at launch.

Solution

Due to the urgent clinical nature of the disease, Tanner worked with the manufacturer to develop patient screening tools, physician education materials, awareness building plan, and provided a mechanism for real world data capture. Tanner developed a robust supply chain process to ensure product integrity and rapid delivery. Tanner also helped to develop and implement a policy for providing free of charge shipments into key markets.

Outcome

Within the first 6 months of going live, Tanner secured access approvals for 44 patients in key European commercial markets and is continuing to enroll patients into a chargeable global early access program. Tanner is also assisting with patients transitioning from named patient to commercial supply country by country.

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CASE STUDY

European Name Patient Program to Bridge to Commercial Supply

Situation

Pharma company's medicine approved by FDA for treatment of pediatric and adult patients with an ultra-rare genetic metabolic disorder. Company needed a partner for a chargeable early access pathway to address unmet medical need for patients in various European countries.

Solution

Tanner worked with the manufacturer to develop a simple but robust process that included a comprehensive supply chain. Tanner worked closely with local HCPs and treatment centres to find and claim funding and to provide justification for treatment while assisting in the process of securing import license applications. Tanner also helped to implement a policy for providing free of charge shipments into key markets to allow more time to obtain funding from local authorities.

Outcome

Tanner provided immediate supply of treatment-enhancing medicine throughout European countries to patients in urgent need by working with local team to coordinate supply of medicine on a named patient basis.

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OUR EXPERTISE

Supporting Clinical Trials Through Product Sourcing, Supply and Logistics

Definition of CTS Services

Sourcing & Supply

- Central or local sourcing:
  - Comparators
  - Ancillary supplies
  - Equipment
  - Labels
- Product quality control
- International transport
- Importation services (IOR)
- Supply chain security
- Pedigree documents
- Supply chain auditing
- Cold chain management
- Technical maintenance

Labelling & Secondary Packaging

- GMP labelling
- GMP secondary packaging
- Batch records
- QP release
- Retention samples
- Serialisation/ randomisation
- Lab-kit building
- Comparator labelling

Storage & Distribution

- Project management:
  - Cost/project budget
  - Quality
  - Service levels
  - Product availability
- Inbound & outbound transport management
- Cold chain management
- Product storage
- Document archiving

Returns & Destruction

- Returns from sites
- Product reconciliation
- Destruction of drugs
- Destruction certificate
- Project close-out

Commercial Services

- LAC
- GAP
- MAP

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TannerGMS Capabilities

Prompted by the outbreak of COVID-19, the Global Medical Supplies division (TannerGMS) was built to help deliver necessary COVID-related medical supplies to patients, organizations and governments around the world.

We work with our PPE and diagnostic manufacturing partners and utilize our direct distribution pathways to create positive solutions and enhance global health.

CORONAVIRUS RAPID ANTIGEN TESTS

- CE ma for symptomatic & asymptomatic use
- Part of the nasal specimen collection
- Rapid testing within 15 minutes
- Facilitates quick patient treatment decisions
- Kit sizes: 1/2/3/5/7/10/15/20 (tests per kit)

PERSONAL PROTECTIVE EQUIPMENT (PPE)

- Syringes/Needles
- Disposable Face Masks
- KN95 Face Masks
- Hand Sanitizer Gel
- Nitrile Medical Gloves
- Disposable Surgical Gowns

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Let’s Make a Difference, Together.