

A photograph of three young adults (two men and one woman) sitting on a rocky cliff overlooking the ocean. They are all smiling and looking at a smartphone held by one of the men, as if taking a selfie. The woman is in the center, wearing a floral crop top. The man on the left has curly hair and sunglasses. The man on the right has glasses and is wearing a denim jacket. The background shows a clear blue sky and the ocean. A teal and dark blue geometric graphic is overlaid on the right side of the image.

# **SHIELD THERAPEUTICS**

## **Investor Presentation**

March 2022

A Potential Best in Class Oral Iron Replacement Therapy

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# Investment Highlights

## Significant Unmet Need

for effective, well-tolerated iron replacement therapy for iron deficiency, a 15MM patients & 13.4MM annual prescriptions opportunity

## Potential Best in Class

approved product, Accrufer<sup>®</sup>, designed to treat iron deficiency with minimal gastrointestinal adverse events which drive treatment discontinuation & failures

## Experienced New Executive Team

to build the business and drive market adoption and revenue growth in the US & Rest of World

## Near Term Value inflection Catalysts

from expanded reimbursement, increasing sales & commercial partnerships

## Market Cap<sup>1</sup>

~\$65MM as of 1 March 2022 provides an attractive entry point





## Cash and Accrufer<sup>®</sup> Market Potential

\$15MM cash as of 31 December 2021  
\$2.2B U.S. market opportunity  
Patent coverage thru 2035

## Operational & Financial Highlights

- **Awareness of Accrufer® among target prescribers doubled since launch to 65%**
- **Generated ~2500 prescriptions for Accrufer® since launch in July 2021 with significant quarterly growth**
- **Payer coverage increased from 40M to 60M commercial lives since last update in December 2021**
- **60% (YoY) growth in Feraccru® sales volumes in Europe**
- **Total Revenue of £1.5M**
- **Cash on Hand Dec 2021: £12.1M**

# Ex-US Partnerships – Update on Progress

Partner	Geography	Status
	China, Hong Kong, Macau and Taiwan	Pharmacokinetics study completed Enrolling Phase 3 clinical trial
	Europe, Australia and New Zealand	60% Y/Y volume increase (EU) Reimbursement dossier submitted for Spain
	Republic of Korea	Program/regulatory strategy in development
	Canada	Program/regulatory strategy in development



# U.S. Market for Accrufer®- \$2.2B Opportunity

## Iron deficiency with or without anemia

- 15MM patients
- A major source of morbidity and mortality

## Adverse events associated with conventional oral iron are

driving an unsatisfactory cycle of switches and discontinuations

Accrufer® is an effective, well tolerated low-dose oral iron with an adverse event and discontinuation rate well below published 40-60% rate for conventional oral iron therapy.

## Estimated Peak Net U.S. Sales of \$500MM+ supported by:

- **Payor Coverage:** Expected to grow beyond 60MM+ covered lives
- **Positive Market Feedback:** HCPs are interested in using Accrufer® for 1<sup>st</sup> and 2<sup>nd</sup> line therapy
- **Commercial Plan:** Focused on the top 65K prescribers, mainly PCPs and OB/GYNs

# Iron Deficiency (ID) without & with Anemia (IDA): 15MM U.S. Patients:

A Source of Morbidity and Mortality

**Caused by** malnutrition, malabsorption, or bleeding

**Associated with** many diseases, especially women's health, IBD, CKD, CHF, oncology, aging

**Results in** numerous signs, symptoms, and negative outcomes across a range of body systems

**IDA may further exacerbate** chronic inflammatory conditions, with even mild anemia leading to increased mortality



Increased risk of preterm labor, perinatal complications, newborn and maternal mortality in pregnancy



Higher IBD symptom burden  
Decreased QoL in IBD



Higher pre-dialysis mortality and ESRD  
Higher CV hospitalizations in CKD



Fatigue, tachycardia, cardiac murmur, angina, dyspnea  
Increased hospitalizations



Headache, vertigo, syncope  
Cognitive impairment  
Restless legs syndrome



Higher morbidity, mortality, hospital length of stay, and re-admissions in major surgery

# Current ID Treatment Options: 90% of Prescriptions are Oral

## Oral



- ✓ Convenient, readily available
- ✗ Less efficient absorption
- ✗ **Poor tolerability**
- ✗ Slower iron repletion
- ✗ Exacerbation of IBD
- ✗ **Poor compliance often due to adverse events**
- ✗ Risk of iron overload due to overdose

## IV



- ✓ Fast iron repletion
- ✓ Better bioavailability and absorption
- ✓ No compliance issues
- ✗ **Inconvenient**
- ✗ **Infusion required**
- ✗ Risk of anaphylaxis
- ✗ Risk of iron overload due to overdose

Poor Tolerability/Inconvenience Drives Poor Adherence

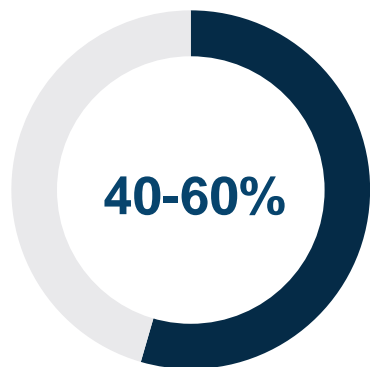


SHIELD  
THERAPEUTICS PLC

IBD, inflammatory bowel disease



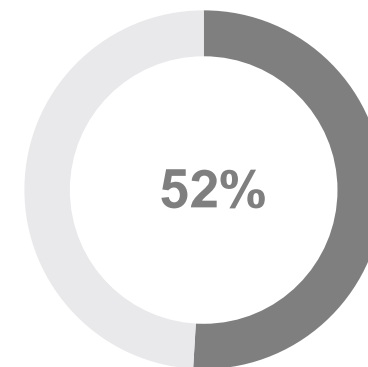
# Adverse Events Associated with Current Oral Iron Treatments Can Limit Patient Adherence



Estimated overall adherence with oral iron for IDA due to *all* AEs<sup>1</sup>



Estimated overall adherence with oral iron for IDA due to GI AEs<sup>2</sup>



Of IBD patients with IDA reduce or withdraw oral iron dose due to AEs<sup>3</sup>

**Non-adherence Can Lead to Substantial Treatment Failures<sup>2</sup>**

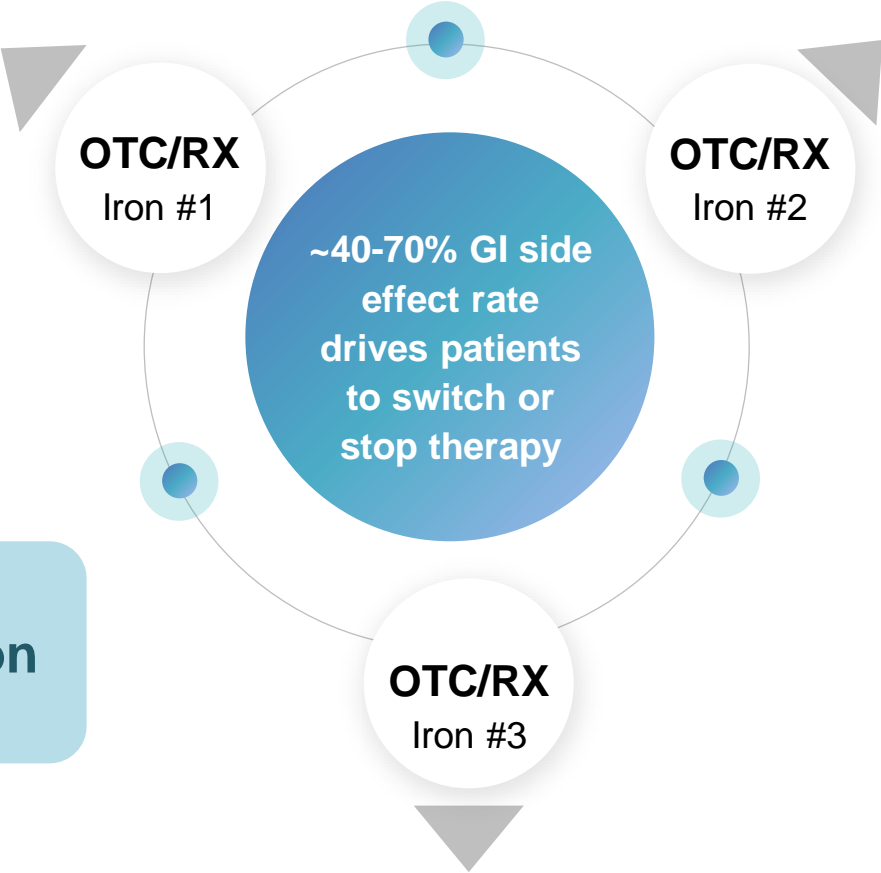
# Iron Deficiency Treatment Algorithm

An Unsatisfactory Cycle of Switches and Discontinuations



OTC/Generic RX Oral Iron

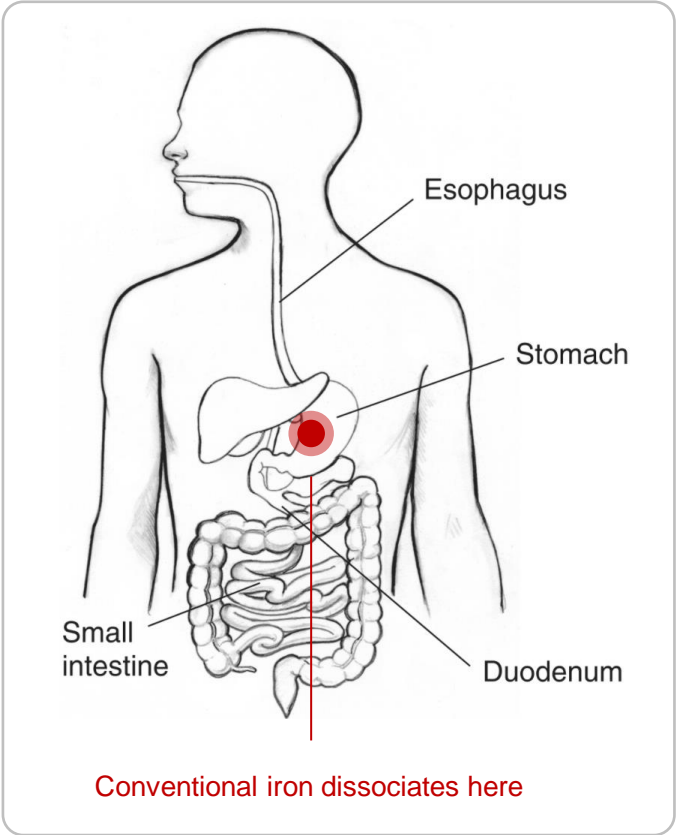
 = Stop Treatment



Patients and Health Care Providers (HCPs) are Seeking a Well-Tolerated and Effective Oral Iron Replacement Therapy

# Design of Conventional Ferrous Iron Products Require High Doses of Iron

Conventional Iron	Formulated as a ferrous salt taken 1-3X/day
Dose	~300 mg daily dose of elemental iron required to achieve therapeutic hemoglobin increase
The Problem	(1) Ferrous salts dissociate prior to intestinal uptake <sup>1</sup> (2) Inefficient absorption results in residual free iron in the gastro-intestinal tract <sup>2</sup>
The Conventional Solution	Increase the dose of elemental iron
Impact	(1) Higher doses of elemental iron generate reactive oxygen species (2) This damages the gastric mucosa & increases the risk of GI adverse events <sup>3</sup>

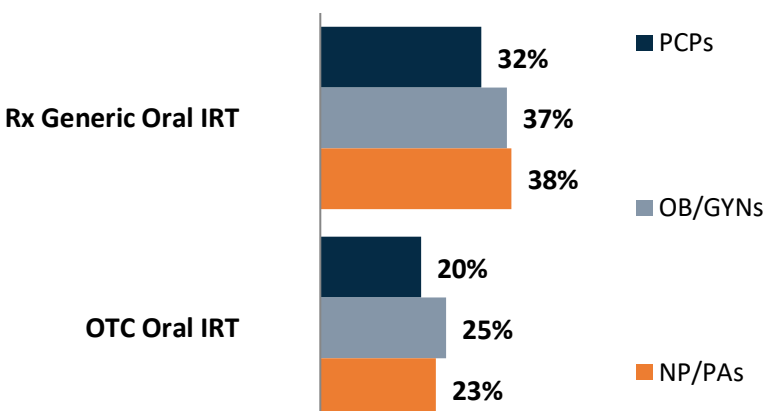


## The Math on Conventional Oral Iron Supplements

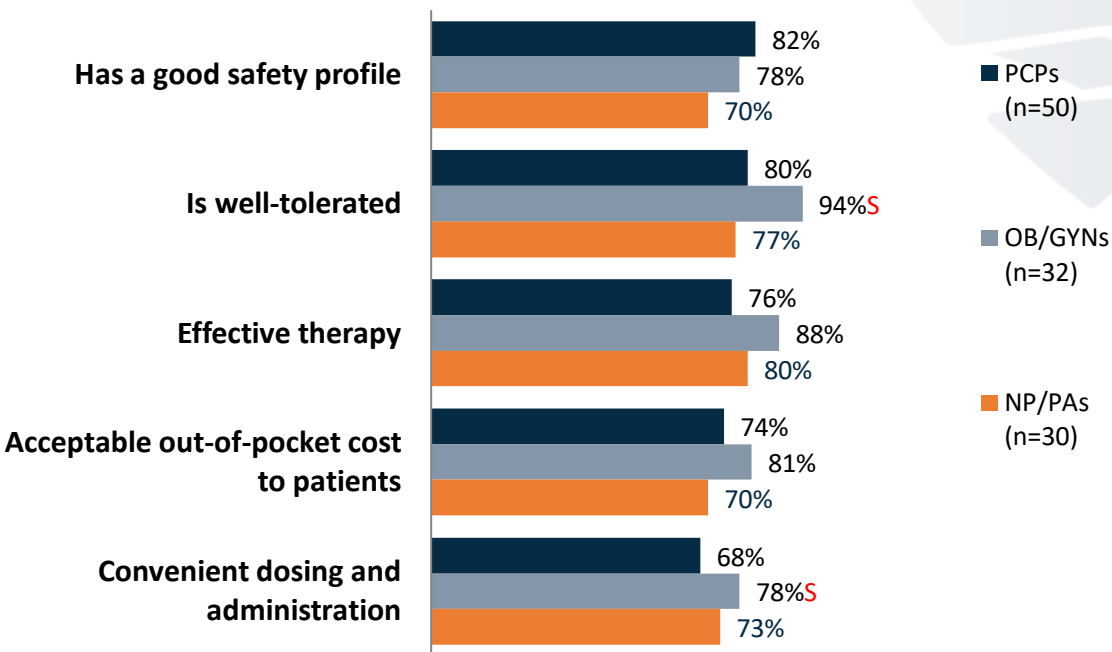
The Product	Elemental Iron per Tablet	Daily Dosing Frequency	Elemental Iron Delivered
Ferrous Salts	~106 mg	1-3X	~300mg

# HCPs have low satisfaction rates with available oral iron treatments

Satisfaction with Iron Deficiency Treatment  
% rating 6,7 (Top-2 Box)



Stated Importance When Selecting IRT (Top Mentions)  
% rating 6,7 (Top-2 Box)



## Reasons for Oral IRT Discontinuation

- Roughly two-of-five patients discontinue oral IRT, usually due to GI side effects.
- Patients are likely encouraged to continue therapy and manage side effects, though Specialists more often switch patients from an oral to IV therapy.

## Top GI Side Effects Experienced

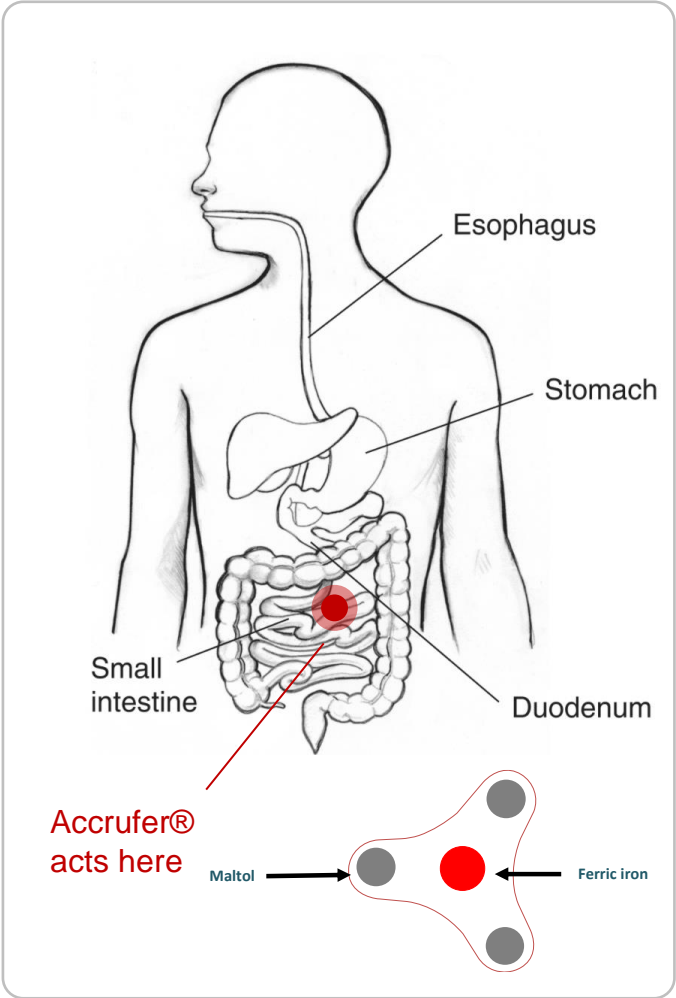
- Constipation
- Nausea
- Abdominal Pain

↑/↓ indicates a significant difference between waves (at a 95% confidence level). Base: Total Respondents. P/B/N/S indicates a significant difference between subgroups at a 95% confidence level.  
Note: NP/PAs and Nephrologists (within Specialists) are new to Wave 1 and are not comparable to baseline. Specialists include Hem/Oncs, Gastros, and Nephs. Note: Questions and scales in notes section.

# Accrufer® is a Novel Formulation of Oral Iron

<b>Accrufer®</b>	Proprietary maltol formulation, dosed 2X/day <sup>1</sup>
<b>Dose</b>	Daily doses of ~60 mg of elemental iron significantly increased hemoglobin levels over 12 weeks, maintained over 52 and 64 weeks across studies <sup>1</sup>
<b>Well Tolerated</b>	Good tolerability, bioavailability and absorption <sup>1</sup> <5% adverse event & discontinuation rate <sup>1</sup> , well below published 40-60% discontinuation rate for conventional oral iron therapy
<b>Safety</b>	Neither short- nor long-term treatment led to iron overload <sup>1</sup>
<b>Accrufer®</b>	Effective at One-Fifth the Dose of Conventional Oral Iron

The Product	Elemental Iron per Tablet	Daily Dosing Frequency	Elemental Iron Delivered
Ferric maltol <sup>1</sup>	30 mg	2X	60mg
Ferrous salt	~106mg	1-3X	~300 mg



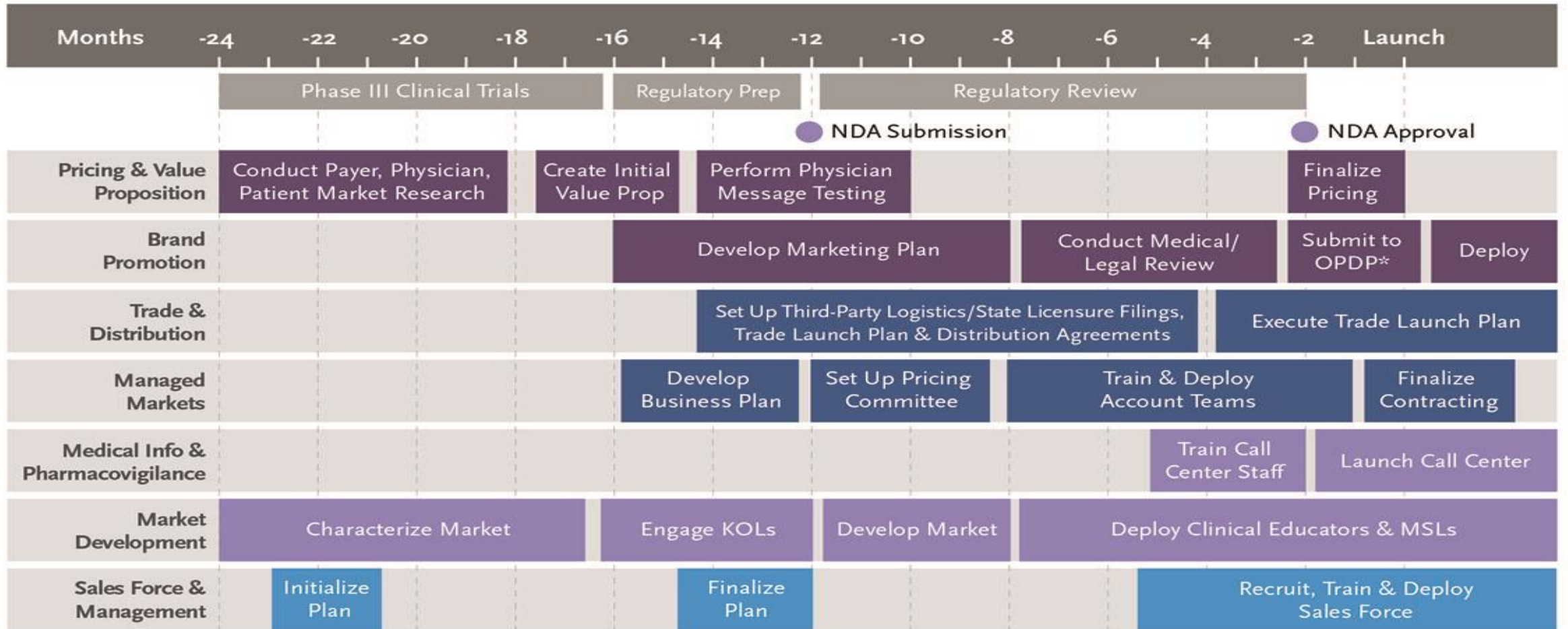
# ACCRUFER® US Launch

(ferric maltol)





## Prepare for Launch with an Integrated Approach

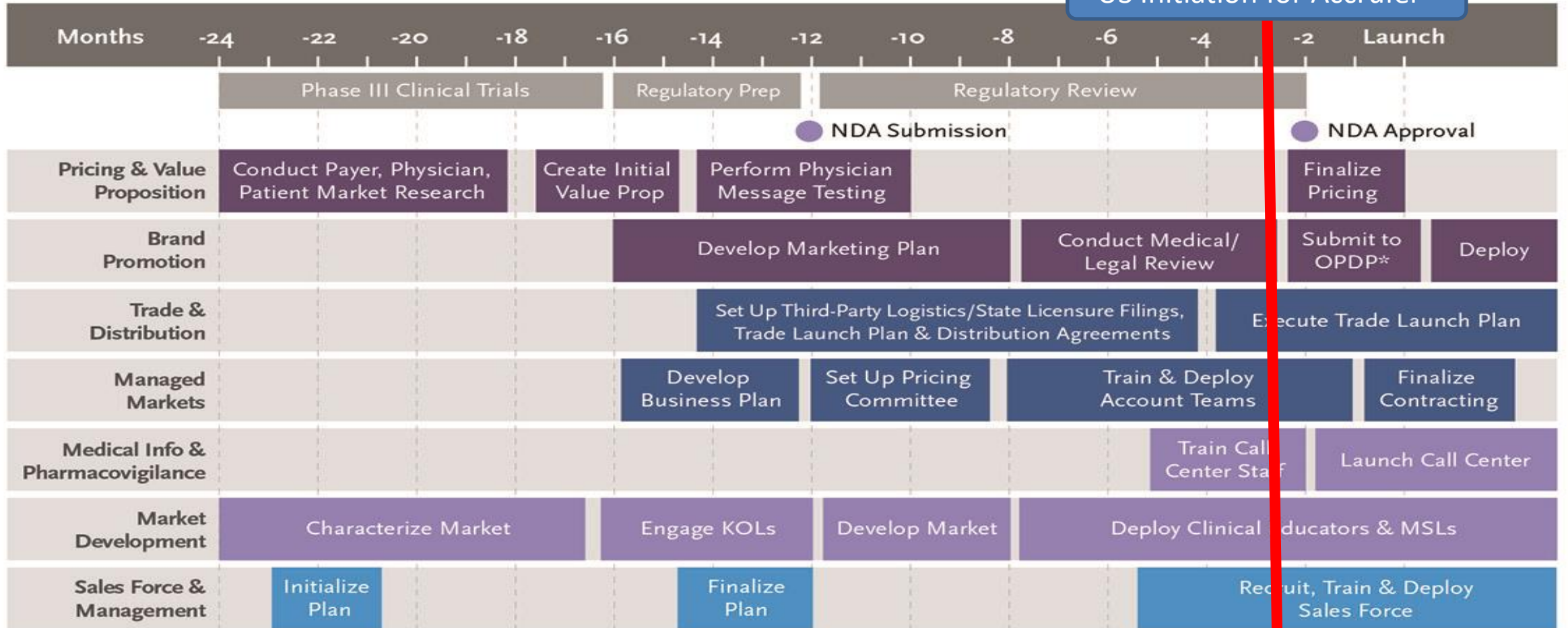


\*Office of Prescription Drug Promotion

Fig. 2: Quintiles' timeline for a commercial launch starts 24 months prior to launch. *Credit: Quintiles*

## Prepare for Launch with an Integrated Approach

US Initiation for Accrufer®



\*Office of Prescription Drug Promotion

Fig. 2: Quintiles' timeline for a commercial launch starts 24 months prior to launch. *Credit: Quintiles*

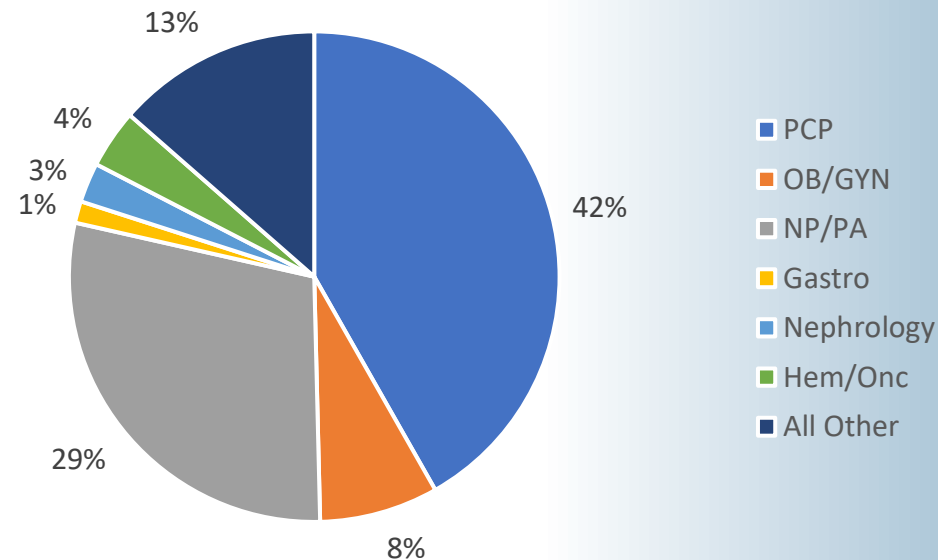
# Accrufer® Launch Priorities



**Long Term Future:** Brand Leader in Oral Iron Therapy

# HCP Targeting Launch Strategy

Oral Iron Market TRx Volume by Specialty



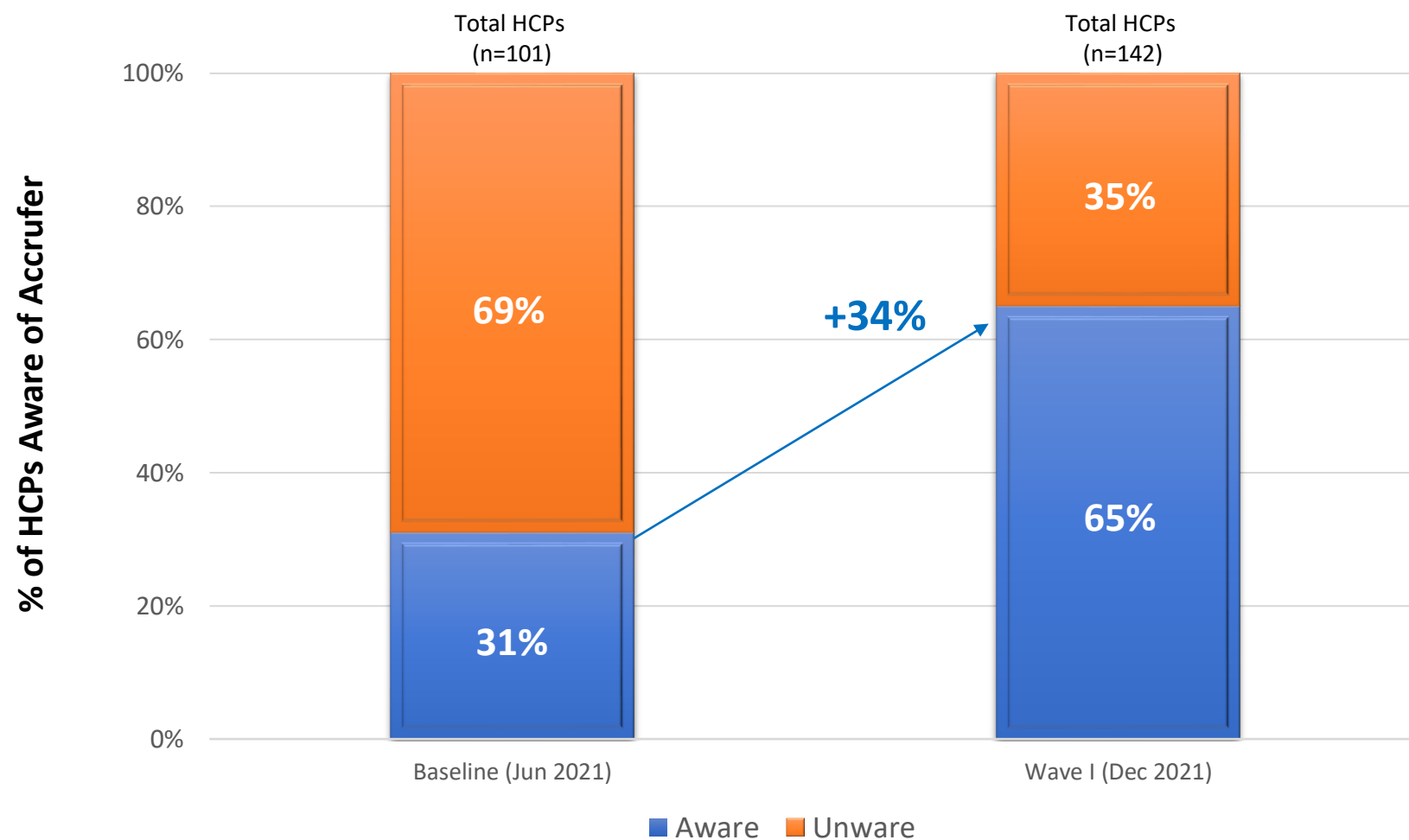
Oral TRx Volume by Specialty

**~4K HCPs**  
~11% TRx Oral Market Volume  
30 sales reps in field in H2:2021  
covering 4,000 high prescribing HCPs

**~61K HCPs**  
~55% TRx Oral Market Volume

**550K HCP Universe**  
13.4MM (100%) TRx  
Oral Market Volume

# Positive Increase in Awareness Among Targeted HCPs



Aided Awareness: Which best describes your level of experience/familiarity with the therapy below for the treatment of patients with Iron Deficiency or Iron Deficiency Anemia (ID/IDA)? HCP specialties included: Baseline (PCPs, OB/GYNs, Gastroenterologists and Hematologists/Oncologists), Wave I (PCPs, OB/GYNs, Gastroenterologists, Hematologists/Oncologists, Nephrologists and NP/PAs).

# HCP Multi-Channel Engagement

## Media & Digital Platforms

Objective: drive brand awareness & education

Utilize media mix to reach clinicians

- Targeted Display
- Search
- Newsletters
- Endemic Site Placements
- Content Sponsorships
- EMR/EHR

Full media plan began 10/1/2021



Medscape

doximity

epocrates



AD+PRIME

Google

NEJM  
GROUP

SKIPTA  
OUR SPECIALTY IS CONNECTING YOURS

TI Health  
TARGETING INTELLIGENCE

BulletinHealthcare

RXNT

JAMA The Journal of the  
American Medical Association



# Accrufer® Launch Priorities



**Long Term Future: Brand Leader in Oral Iron Therapy**

# Driving Clinical Experience through Patient Assistance Program

Accessing Accrufer® Through

**CoAssist**

**CoAssist offers the lowest copay and convenient at-home delivery for commercially insured patients.\***

Your doctor has sent your prescription to CoAssist, which is the dedicated pharmacy for Accrufer (ferric maltol).

CoAssist will work with your insurance company directly to verify your insurance benefits and provide automatic copay assistance for your prescription.

**Most patients will pay as little as \$10.\***

CoAssist offers free home delivery where appropriate and will send texts directly to your phone confirming prescription and insurance information, reminding you of refills and alerting you that your prescription is on its way.


\*Restrictions and maximum savings limits apply. Coverage and out-of-pocket costs may vary. This offer is valid only for patients with commercial insurance. Offer not valid for patients participating in Medicare, Medicaid, or other government healthcare programs. Additional terms and conditions apply.



**ACCRUFER®**  
(ferric maltol) 30 mg capsules


**CoAssist**

**Automated Accrufer® therapy initiation and prescription fulfillment for your commercially insured patients**




**E-prescribe Accrufer script to CoAssist Pharmacy**

- eRx: NCPDP: 5733604 or NPI: 1588101356
- Phone: 855-382-2533 | Fax: 833-596-2174
- Monday – Friday, 9 AM – 5 PM ET




**Benefit investigation is automated through an exclusive technology-driven pharmacy platform**

- A benefit investigation is conducted at the point of prescription to access the most up-to-date information and payer requirements




**Script is routed to best fulfillment option for patient**

- CoAssist pharmacy ensures access to prescribed therapy and is a patient affordability-centered pharmacy model
- Your patient will receive a welcome text from CoAssist within 1 business day of receiving the prescription letting them know the prescription was received and it is being processed
- CoAssist will also text or call the patient if additional insurance information is required and to collect any copay amount




**Script is dispensed to patient**

- Accrufer is delivered for FREE straight to your patient's door in 3 to 5 business days from the day of patient consent and payment
- Your patient will receive text notifications and tracking information for their delivery, as well as ongoing medication refill reminders

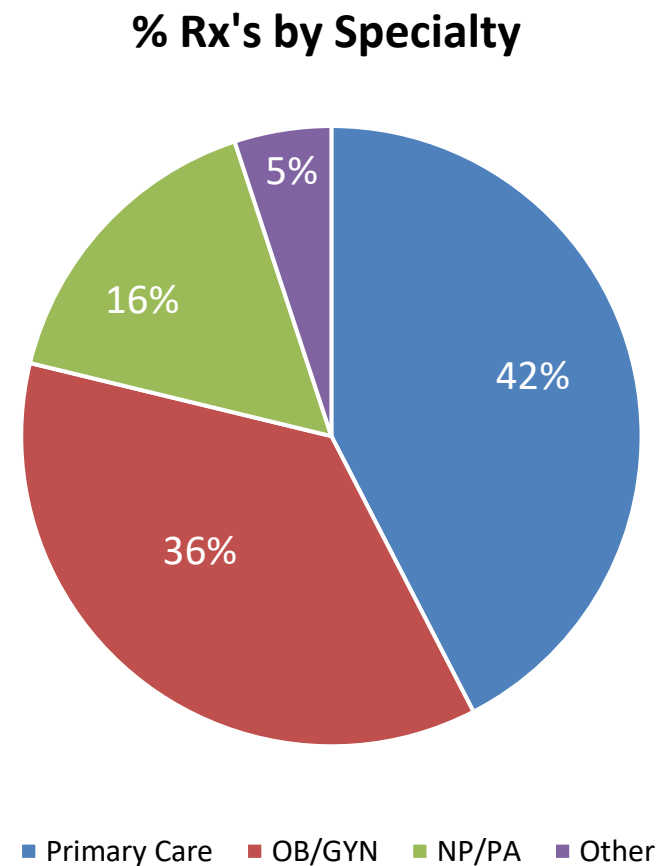
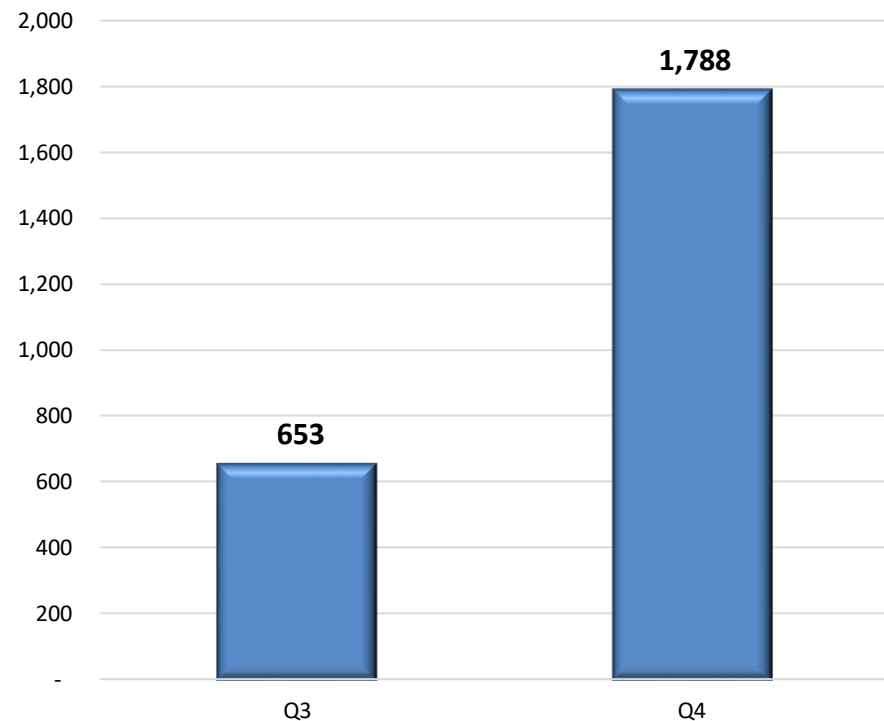


**SHIELD**  
THERAPEUTICS



**ACCRUFER®**  
ferric maltol 30 mg capsules

# Health Care Professionals (HCPs) Demand Increasing

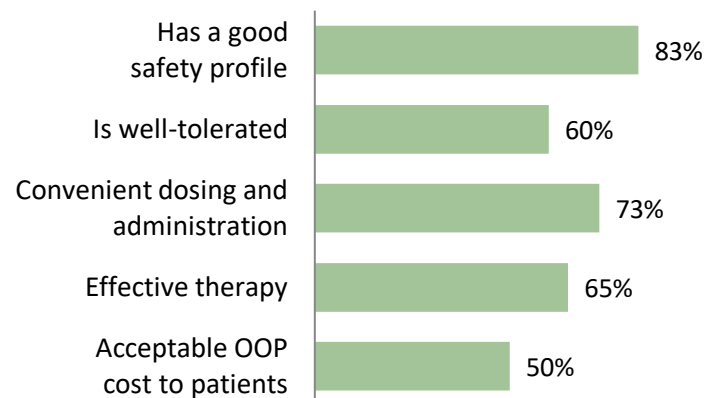


# HCPs report Accrufer® performs WELL where it matters most

## Accrufer® Performance

% rating 5, 6,7 (Top-3 Box)

Among Attributes Rated as Most Important (n=40)



### ADVANTAGES (UNAIDED)

- ⊕ Well tolerated
- ⊕ Effective
- ⊕ Less GI/constipation side effects
- ⊕ Oral administration



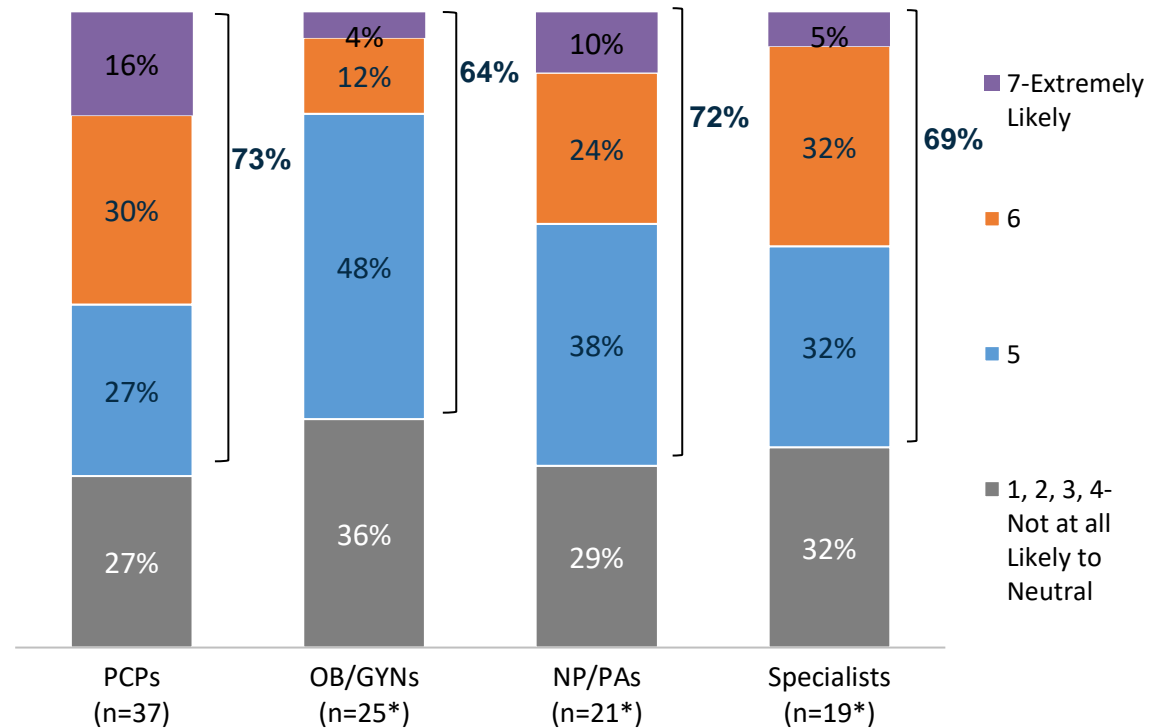
### DISADVANTAGES (UNAIDED)

- ⊖ Cost
- ⊖ Insurance Coverage

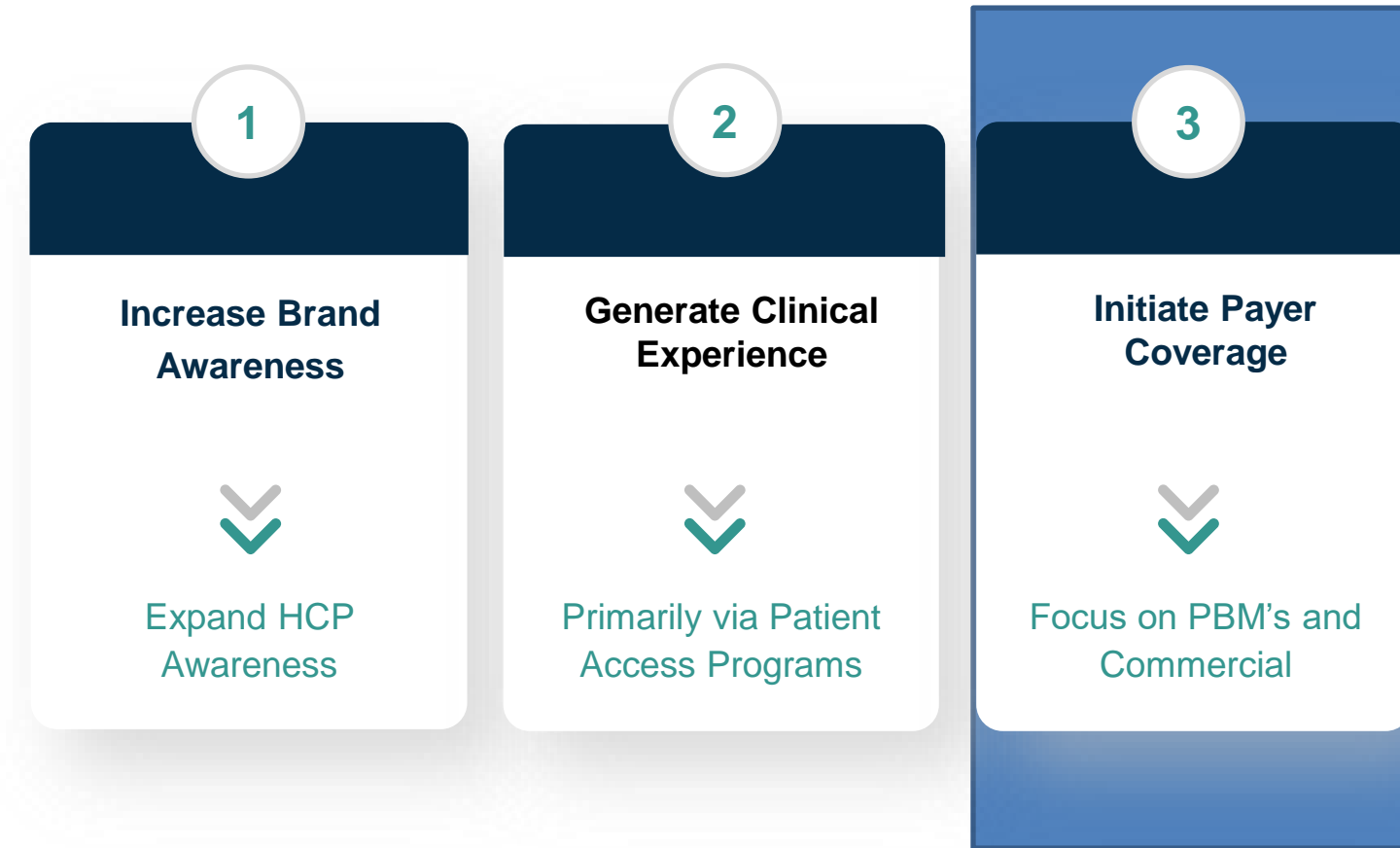
# HCP's who have never used Accrufer® indicate they are likely to prescribe

Accrufer  
Non-Users

## Likelihood to Prescribe Accrufer



# Accrufer® Launch Priorities



**Long Term Future:** Brand Leader in Oral Iron Therapy



# Payer Access Increased in January – 40m (Dec) up to now 60M+ Lives Covered

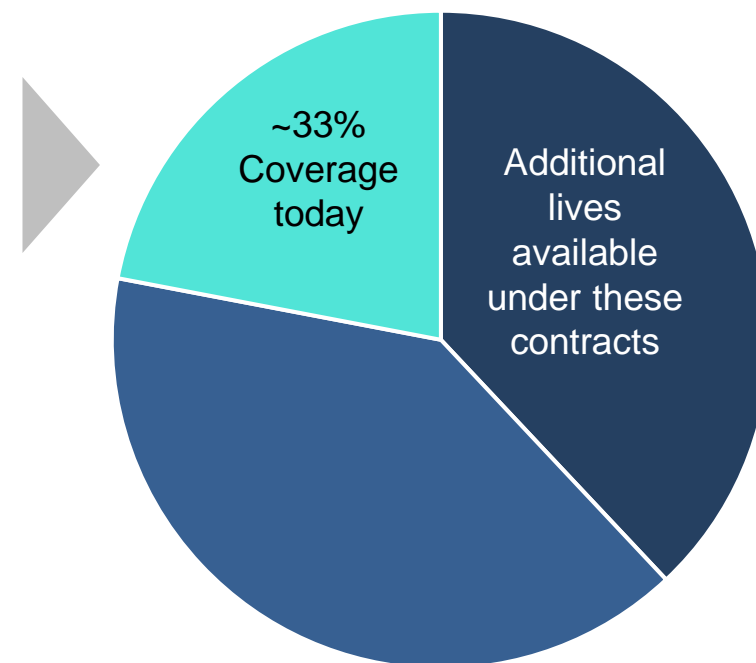
December 2021



January 2022



Commercial Payers, % Covered Lives



## Observations and Insights from First Six Months

- **Accrufer<sup>®</sup> Awareness is critical – while increasing, a lot of room to grow**
- **Key messages around tolerability and effectiveness is on point – continue to reinforce**
- **Payer coverage continues to grow**
- **Evolution of the organization and approach on-going**

# Accrufer® 2022 Priorities

1

**Increase Brand Awareness**



Expand HCP Awareness

2

**Expand and Accelerate HCP Adoption**



Drive Breadth and Depth of Prescribing

3

**Minimize Patient Barriers to Access**



Expand Payer Coverage

4

**Raise Awareness and Activate the Patient**



Utilize Digital and Social Media to Efficiently Target Patients

# Q&A Discussion

