

KNOW YOUR IBD
WEBCAST SERIES FOR PATIENTS

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WHAT TO KNOW ABOUT
Biologic Therapy
IN IBD

These programs are supported by educational grants from Janssen Biotech, Inc., administered by Janssen Scientific Affairs, LLC, and AbbVie. It is also supported by a sponsorship from Takeda.

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Program Goals

- Review use of biologic therapy in Crohn's disease and ulcerative colitis
- Help you understand risks and benefits of therapy
- Discuss importance of adherence to treatment
- Share resources to help you monitor your disease

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Poll Question #1

Which best describes you?

- A. I am a patient with Crohn's disease
- B. I am a patient with ulcerative colitis
- C. I am a friend/family member of a patient with Crohn's disease
- D. I am a friend/family member of a patient with ulcerative colitis
- E. Other

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IBD Medicine Cabinet

- Over-the-Counter Medications
- Aminosalicylates
- Corticosteroids
- Immunomodulators
- Antibiotics
- **Biologic therapies**

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Poll Question #2

Test your knowledge on Biologics

Which of the following statements is False?

- A. Biologics are grown in living cells
- B. Biologics target particular proteins, chemicals, or cells
- C. Biologics are chemically made

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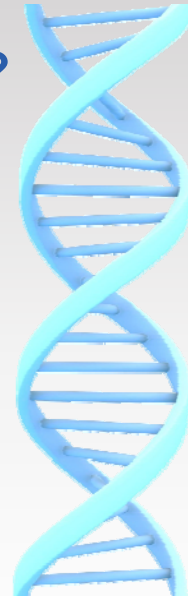
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What are Biologics?

- Many include proteins or antibodies which are part of the immune defense
- They are medicines made from living organisms
- Similar or identical to the actual biologic chemicals that our body makes
- Historically reserved for patients not responding to standard therapies, but increasingly used earlier in the course of treatment



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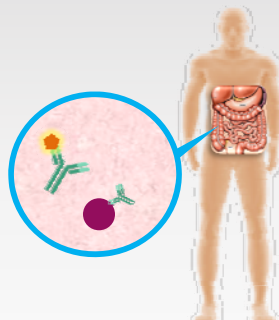
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Mechanism of Biologics

- How do they work?
 - Antibodies bind and help eliminate infections
 - Molecules bind to components of inflammatory process
- Block protein called tumor necrosis factor (TNF), made by white blood cells that can promote inflammation
- Block interaction between receptors on white blood cells with receptors on surface of intestinal lining



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Overview of Biologics

- How are they different than other therapies?
 - Biologics are more complex
 - 1,000 times larger than conventional medicines
 - Mechanism of action is targeted to particular proteins, chemicals, or cells
 - Unlike corticosteroids, biologic agents act selectively

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Types of Biologics: Anti-TNF Drugs

Adalimumab (Humira®)	<ul style="list-style-type: none"> • Taken as subcutaneous (under skin) injection • Indication: Crohn's disease (adult and pediatric) and ulcerative colitis (adults) • Most effective for patients for whom conventional therapies fail
Certolizumab Pegol (Cimzia®)	<ul style="list-style-type: none"> • Taken as subcutaneous injection • Indication: Crohn's disease only (adults) • Most effective for maintaining clinical response; patients with inadequate response to other therapies
Golimumab (Simponi®)	<ul style="list-style-type: none"> • Taken as subcutaneous injection • Indication: Ulcerative colitis only (adults) • Most effective for patients whom conventional therapies fail; to induce and maintain clinical response, remission
Infliximab (Remicade®)	<ul style="list-style-type: none"> • Taken as intravenous (IV) infusion • Indication: Crohn's disease and ulcerative colitis (adult and pediatric) • Most effective for maintaining remission; treating fistulizing Crohn's

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Types of Biologics: Anti-TNF Drugs

Adalimumab (Humira®)	<p>Common side effects include injection/infusion site reactions, risk of infections, psoriasis-like reaction</p>
Certolizumab Pegol (Cimzia®)	
Golimumab (Simponi®)	
Infliximab (Remicade®)	

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Risks Associated with Anti-TNF Treatment

Event	Estimated Frequency (annual)
Stop therapy	10% (10/100)
Infusion or injection-site reactions	3%-21%
Drug-related lupus-like reaction	1% (1/100)
Serious infections	3% (3/100)
Non Hodgkin's Lymphoma (combination)	0.06% (6/10,000)
Multiple sclerosis, heart failure, serious liver injury	Case reports only

Siegel CA. *Inflamm Bowel Dis.* 2010;16(12):2168-2172.

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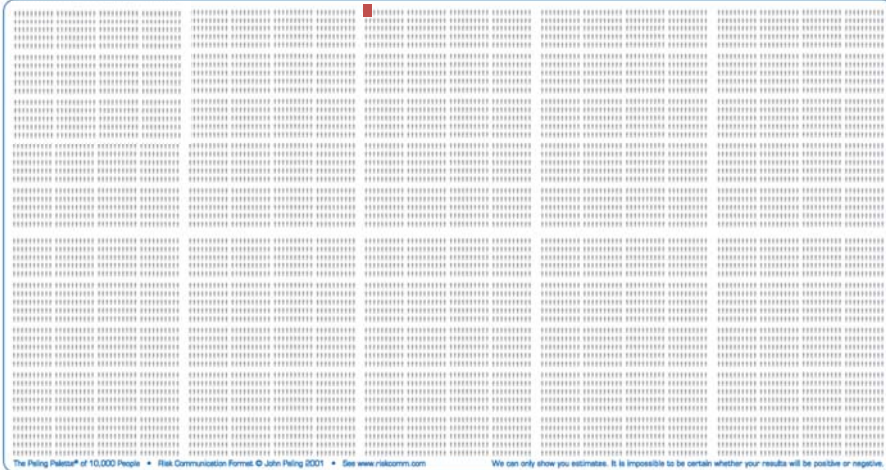


Risk of Developing Non-Hodgkin's Lymphoma

Patient with Crohn's disease

Ten Thousand People
- pictures to help you see your odds

Estimated annual risk =
2 per 10,000 treated patients

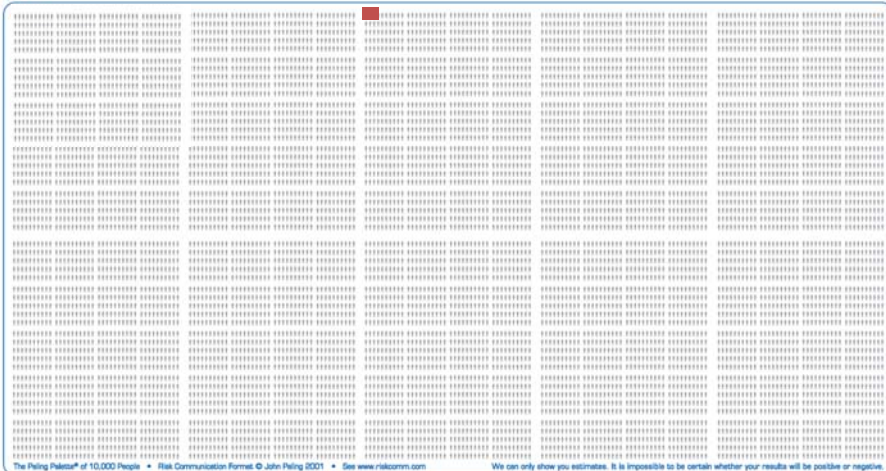


Risk of Developing Non-Hodgkin's Lymphoma

Patient with Crohn's disease receiving 6MP or Azathioprine

Ten Thousand People
- pictures to help you see your odds

Estimated annual risk =
4 per 10,000 treated patients

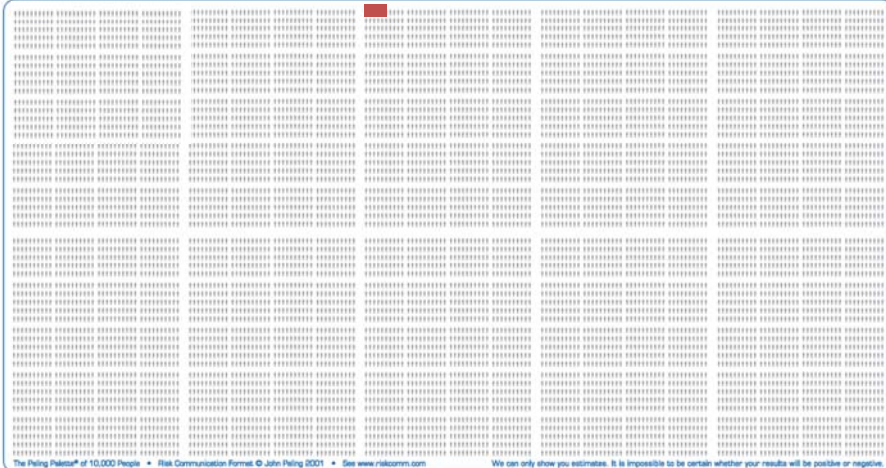


Risk of Developing Non-Hodgkin's Lymphoma

Patient with Crohn's disease receiving combination anti-TNF + Immunomodulator Therapy

Ten Thousand People
- pictures to help you see your odds

Estimated annual risk =
6 per 10,000 treated patients



Types of Biologics: Integrin Receptor Antagonists

Natalizumab
(Tysabri®)

- Taken Intravenous (IV) infusion
- **Indication:** Moderate-severe Crohn's disease **only** (adults)
- **Most effective to** Induce and maintain clinical response and remission

Vedolizumab
(Entyvio®)

- **Taken:** Intravenous (IV) medication
- **Indication:** Moderate-severe Crohn's disease **and** ulcerative colitis (adults)
- **Most effective** for achieving corticosteroid free remission and
 - **UC:** inducing and maintaining clinical response and remission; improving mucosal appearance
 - **CD:** achieving clinical response and remission

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Integrin Receptor Antagonists: Risks

Natalizumab (Tysabri®)	<ul style="list-style-type: none"> Rare brain infection PML (blood test required prior to treatment) – screen for John Cunningham Virus Liver damage
Vedolizumab (Entyvio®)	<ul style="list-style-type: none"> Slightly increased risk of colds (nasopharyngitis)

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Special Considerations

- Pregnancy**
 - Studies show better prognosis if disease is inactive at time of conception
 - Biologic drug safety categories; biologics:

Biologic medication	Pregnancy Recommendations	Breast-feeding recommendations
Certolizumab pegol (Cimzia®)	Low risk	Limited human data
Vedolizumab (Entyvio™)	No fetal harm observed; use only if benefits outweigh risk	Limited human data
Adalimumab (Humira®)	Low risk	Limited human data
Infliximab (Remicade®)	Low risk	Limited human data
Golimumab (Symponi®)	Low risk	No human data
Natalizumab (Tysabri®)	May cause fetal harm	Detected in human milk; effects unknown

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Difficulty with Pediatric Treatments

- Limited data in pediatric IBD therapy
 - Treatment extrapolated from adult studies
 - Not “one size fits all”
- Concerns of drug toxicity
 - Infections
 - Cancer
 - Impact of lifetime therapy duration
- Outcomes for clinical trials needs to consider pediatric-specific outcomes



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Therapeutic Monitoring

- Measure drug concentrations and antibody levels (currently infliximab and adalimumab, others to come)
- Helps to understand
 - If dosage is sufficient
 - If patient has developed antibodies to the drug
- Results can guide decisions for how to optimize medications that are working, or tell us when to move on
- Your doctor can “personalize” treatment by monitoring biologic therapy

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Option Grids

<http://www.optiongrid.co.uk>



Crohn's Disease Treatments
Use this grid to help you and your clinician decide on the best initial treatment for your disease.

	Immunomodulator Azathioprine (Imuran, Azasan); 6-mercaptopurine (6MP); Methotrexate	Anti-TNF Infliximab (Remicade); Adalimumab (Humira); Certolizumab pegol (Cimzia)	Combination Therapy
What type of medication is this?	An immunomodulator is a medicine that is taken to dampen the body's immune system in order to reduce inflammation in the bowel. This type of medication has been used for over 30 years.	This medication blocks the ability of a tumour necrosis factor (TNF) to cause inflammation, damaging the bowel. Anti-TNF has been used to treat Crohn's since 1998.	Using an immunomodulator and an anti-TNF drug together.
How is this treatment administered?	Daily, as a pill. It may take a month or two to have an effect so you might also use a steroid, such as prednisone, for a few weeks to months.	Remicade is injected into a vein every other month. Humira or Cimzia are given as a shot under the skin every 1 to 4 weeks.	With daily pills plus either an IV (into the vein) treatments every other month, or shots every 1-4 weeks.
How many people get relief and can stay off steroids?	Approximately 30 people out of 100 who take this treatment can stop their steroids (30%).	Approximately 40 people out of 100 who take this treatment do not need to use steroids (40%).	Approximately 60 people out of 100 who take this combined treatment do not need to use steroids (60%).
How many people have complete healing of the ulcers in their intestine?	Approximately 20 people out of 100 on treatment (20%).	Approximately 30 people out of 100 on treatment (30%).	Approximately 40 people out of 100 on combined treatment (40%).
What are some common, but short-lasting, side-effects?	Approximately 3 people out of 100 (3%) develop pancreatitis - where the pancreas becomes painful and damaged. Other short term side effects may include infections like sinusitis or bronchitis.	Allergic reactions that may include a rash, fever, or shortness of breath occur in approximately 5 people out of 100 (5%) receiving treatment.	Frequency of pancreatitis and infections are the same during combination therapy as when taken individually. Allergic reactions to anti-TNFs may occur less often with combination therapy.
How many people stop taking the medication because of side effects?	Approximately 10 people out of 100 (10%).	Approximately 10 people out of 100 (10%).	Approximately 10 people out of 100 (10%).
How common are serious infections?	Approximately 4 people out of 100 (4%) experience serious infections.	Approximately 4 people out of 100 (4%) experience serious infections.	Approximately 4 people out of 100 (4%) experience serious infections.
What is the risk of getting Non-Hodgkin's lymphoma?	The risk is that approximately 4 people out of 10,000 get lymphoma (0.0004%), compared to a risk of 2 in 10,000 if you are not on immunomodulators.	The risk is that approximately 4 people out of 10,000 get lymphoma (0.0004%), compared to a risk of 2 in 10,000 if you are not on anti-TNFs.	The risk is that approximately 6 people out of 10,000 get lymphoma (0.0006%), compared to a risk of 2 in 10,000 if you are not on this treatment.

CD Decision Aid Sample Clips

Benefits

Landmark study
The information about these medications comes from a very important landmark study that was done by testing a group of 500 people with Crohn's.

Risks

How common are bad infections?
Bad things can happen to possibly lower the chance of an infection ever happening.

Early Therapy

The graph shows cumulative damage over time, and the pill bottle represents early therapy to reduce this damage.

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Judging Response to Treatment

- How do I know if my treatment is working?

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Judging Response to Treatment

- How do I know if my treatment is working?
- If I am in remission, should I stop my treatment?

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Judging Response to Treatment

- How do I know if my treatment is working?
- If I am in remission, should I stop my treatment?
- How much time should I allow before trying a new medication?

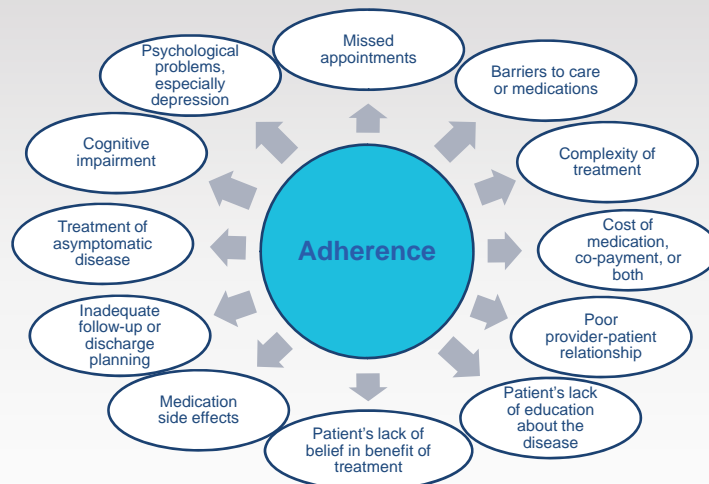
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Adherence is Important!



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Biosimilars

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Poll Question #3

Which of the following is True?

- A. Generic biologic medications are currently available
- B. Biosimilars are identical to biologics
- C. Biosimilars are not generic biologics

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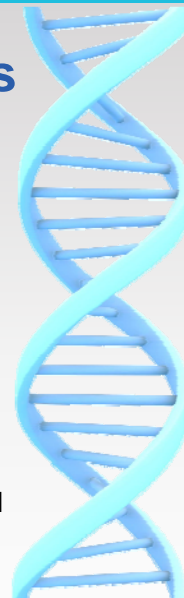
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What are Biosimilars

- Products that are “highly similar” to—but not exact copies of—biologic medicines
- As part of the Affordable Care Act (ACA), Food and Drug Administration (FDA) will review and approve biosimilar versions of FDA approved biologic medicines
- FDA issued guidance's, but has not initiated formal rulemaking
- No US FDA approved biosimilars to date; expected approvals in the near future



Source: Patients for Biologics Safety and Access

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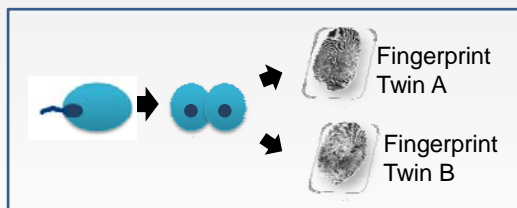
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More on Biosimilars

- Are an effort to develop something like a generic for biologics
- Biosimilars are similar to a particular biologic, but they are not the same
- All biosimilars differ from biologics and from each other
- Biologics medications can not have generic versions
 - Active ingredients can only resemble at best
 - Ex. different fingerprints in identical twins



Source: Patients for Biologics Safety and Access

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Things to Consider about Biosimilars

- Interchangeability
- Rigorous testing
- Naming
- Substitution/notification
- FDA Transparency

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Poll Question #4

Which of these is your biggest concern about biologic therapy?

- A. Risks and side effects of biologics
- B. Insurance benefits and cost
- C. Effectiveness of the treatment
- D. Deciding which treatment to choose
- E. Other

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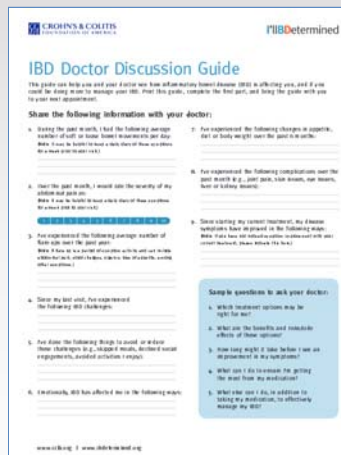
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Talk to Your Healthcare Team

- Which treatment options may be right for me?
- What are the benefits and risks/side effects of these options?
- How long might it take before I see an improvement in my symptoms?
- What can I do to ensure I'm getting the most from my medication?
- What else can I do, in addition to taking my medication, to effectively manage my IBD?

Source: http://www.ibdetermined.org/Common/Documents/ibd_doctordiscussionguide.pdf



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Key Points on Biologic Therapy

- Biologic drugs made from living organisms and resemble chemicals in the body; different from conventional therapy
- Important to consider risks and benefits
- Response to biologics may differ for each person; adhering to treatment can improve outcomes and maintain remission
- Biosimilars would resemble biologics, but are not generic versions
- Communicate with your healthcare team



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References

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 - http://www.ibdetermined.org/Common/Documents/ibd_doctordiscussionguide.pdf
 - <http://www.ccfa.org/resources/biologic-therapies.html>
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- Cryer, D. R. Understanding Biologics & Biosimilars: An Overview-presentation. Patients for Biologics Safety & Access. October, 2014
- Siegel CA. Lost in translation: helping patients understand the risks of inflammatory bowel disease therapy. *Inflamm Bowel Dis*. 2010;16(12):2168-2172.
- Food and Drug Administration website: <http://www.ccfa.org/resources/biologic-therapies.html>
- Irwin M. and Suzanne R. Rosenthal IBD Resource Center (IBD Help Center): 888.694.8872 or info@ccfa.org

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QUESTIONS?

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AGA Resources

- Education :
<http://www.gastro.org/patient-center/digestive-conditions/inflammatory-bowel-disease>.
- Patient guide to GI procedures:
<http://www.gastro.org/patient-center/procedures>
- Patient guide to diets and medications:
<http://www.gastro.org/patient-center/diet-medications>

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CCFA Resources

- Irwin M. and Suzanne R. Rosenthal IBD Help Center
M-F, 9:00 AM-5:00 PM ET
 - Phone: 1-888-694-8872
 - Email: info@ccfa.org
- Educational webcasts: www.ccfa.org/resources/webcasts.html
- Connect with other patients
 - CCFA Community website: www.ccfacommunity.org
 - Support groups and Power of Two (peer mentors):
www.ccfa.org/chapters
- GI Buddy: online tracking tool and mobile app www.ccfa.org/gibuddy
- Local educational events, visit: www.ccfa.org



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CCFA Partners



- Registry of patient-reported outcomes
- Available for pediatric and adult patients

www.ccfapartners.org

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Get Involved!

TeamChallenge
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TAKE STEPS
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WWW.CCTAKESTEPS.ORG

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