ids®
Immunodiagnosticsystems

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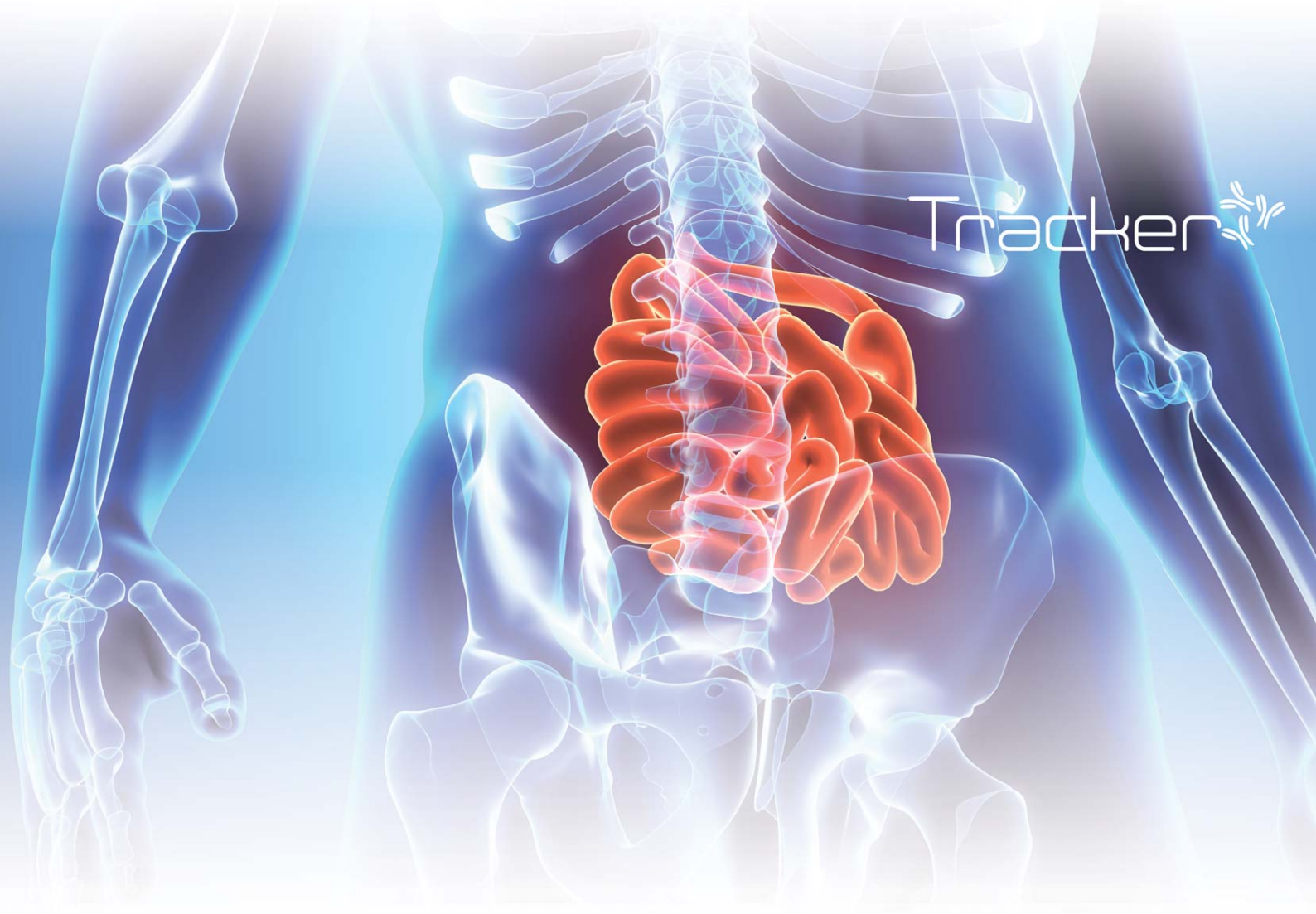
AG



Therapeutic drug monitoring in inflammatory bowel diseases

- **Measurement of biological drug levels and free anti-drug antibodies**
- **Minimising costs and side effects of therapy while maintaining treatment response**

Commitment to innovation

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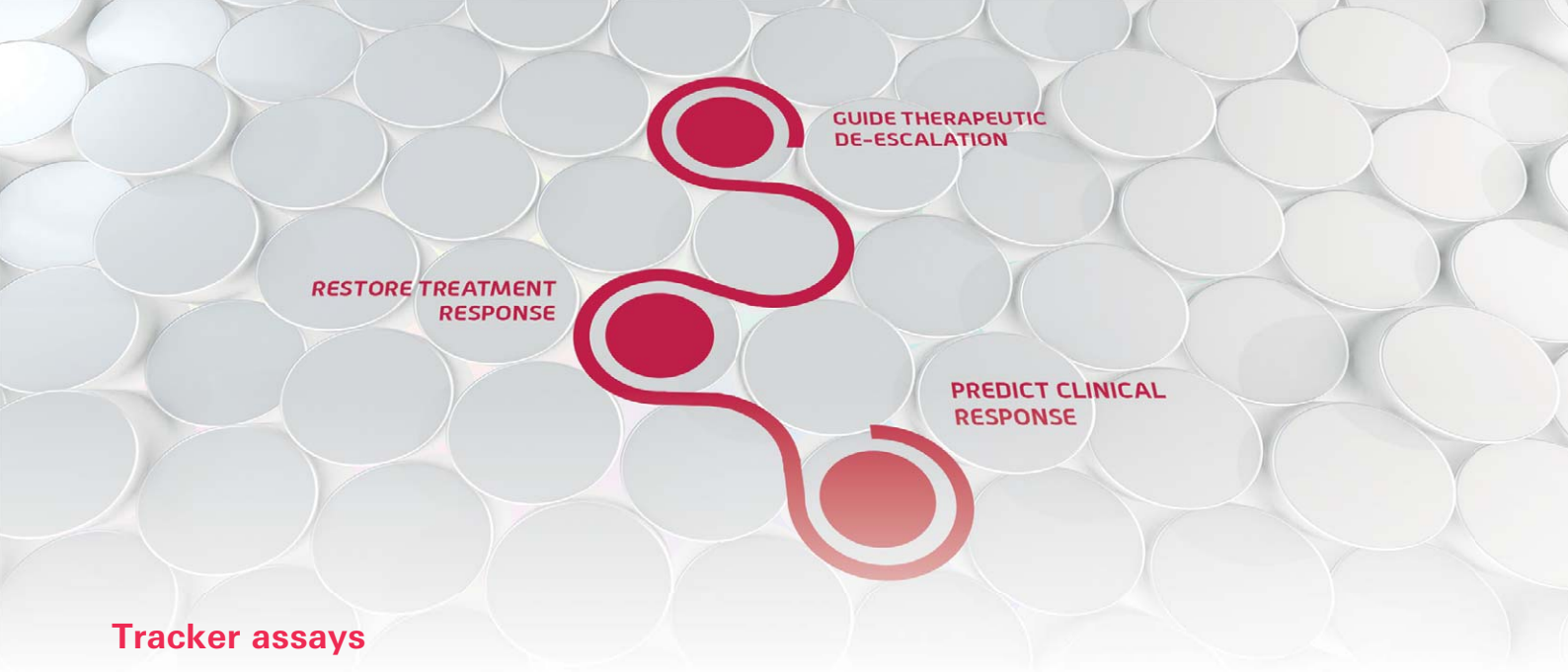


Tracker assays

Your clinical decision making tools for inflammatory bowel diseases (IBD)

Clinically validated

- Suitable for routine use in your clinical practice
- Measurement ranges for both induction and maintenance phase of treatment

Easy to use

- Ready-to-use reagents
- Standardised protocols from sample collection to results interpretation
- Protocols for automated ELISA platforms (EUROIMMUN instruments, DS2, DSX, Evolis) available on request
- Validated with IMMUNO-TROL INTERNAL CONTROL

Clinically relevant

- Numerous publications referring to TRACKER in peer-reviewed journals
- International decision algorithms validated with TRACKER

Therapeutic drug monitoring (TDM) strategy leads to major cost savings in IBD patients while maintaining appropriate efficacy [1]

Accurate

- Accurate quantitative measurement of drug levels and anti-drug antibodies
- Detection of free anti-drug antibodies to adjust therapy to patient's status as recommended by international guidelines
- Performance validated with both original drugs and biosimilars

Cost-effective

TDM allows a significant reduction (by 28 to 50%) in cost of biological therapy [1]

- of ulcerative colitis (UC) and Crohn's disease (CD)
- of patients in remission for therapeutic de-escalation [2]
- of patients with loss of response [3]

Unique TDM solutions

- Comprehensive portfolio for inflammatory diseases and oncology
- CE-IVD validation for serum and plasma samples
- Validation in accordance with the 1st WHO international standards (Infliximab and Adalimumab)
- Validation with both original drugs and biosimilars
- Continuous development for new parameters

TDM for the maintenance phase of biological therapy and the optimal use of drugs

Nearly 20–30% of patients

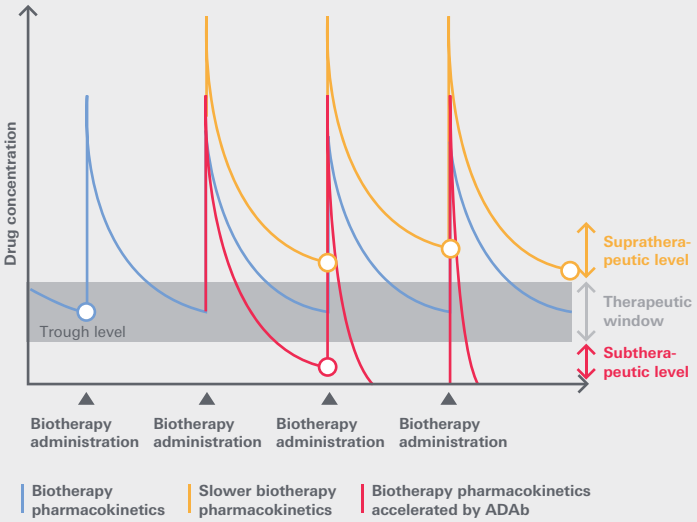
do not respond
to anti-TNFα treatment[4]

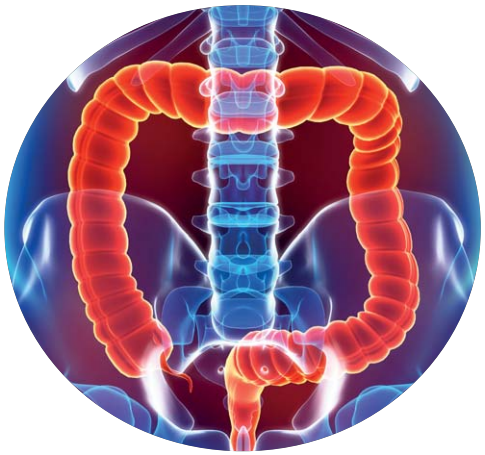
50% of IBD patients

experience relapse in disease activity
during maintenance phase of therapy[5, 6]

Pharmacokinetics and pharmacodynamics of biologics are highly variable.

- Patients with a higher dose of drug or slower pharmacokinetics may have drug trough levels above the therapeutic window (supratherapeutic). Higher trough levels may increase side effects.
- Patients with a lower dose due to the presence of anti-drug antibodies or with a low serum albumin or high baseline CRP concentration may have drug trough levels below the therapeutic window (subtherapeutic), leading to reduced drug efficacy.





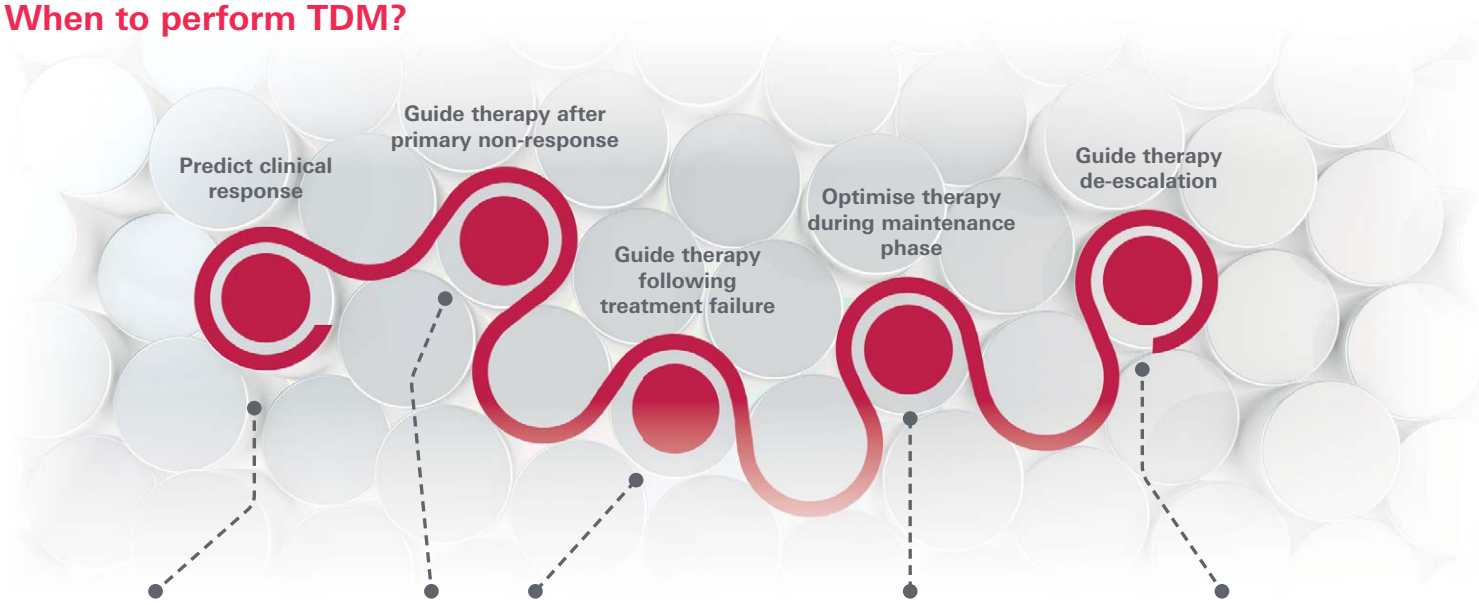
TDM provides key information
to support patient management during IBD therapy

Appearance of anti-drug antibodies (ADAb) varies widely among biologics, regardless of the disease.

Assessment of the immunogenicity of these agents is an important consideration in the treatment decision making process.

Biologic	Immunogenicity in Crohn's disease	Immunogenicity in ulcerative colitis
Infliximab & Infliximab biosimilar (CT-P13)	up to 83%[7]	up to 46%[7]
Adalimumab	up to 35%[7]	up to 5%[7]
Certolizumab Pegol	up to 25%[7]	up to 25%[7]
Vedolizumab	up to 3.7%[7]	up to 3.7%[7]
Ustekinumab	up to 1%[7]	up to 1%[7, 8]
Golimumab	–	up to 19%[9]

When to perform TDM?



Proactive monitoring
Predict short- and long-term clinical outcomes and adjust treatment immediately [10, 11]

Reactive monitoring
Clarify cause of non-response, guide subsequent therapeutic decisions and restore patient response [12–14]

Proactive monitoring
Target therapeutic concentration while minimising cost and side effects [10, 13, 15–17]

Proactive monitoring
Guide therapeutic de-escalation for patients in remission to minimise drug exposure and cost [18–20]

INDUCTION TREATMENT | MAINTENANCE TREATMENT | CLINICAL REMISSION

Interpret dosing information

- Drug levels required to improve clinical outcomes may vary between patients and depend on the therapeutic goal.
- In patients with undetectable drug levels, anti-drug antibody (ADAb) quantification helps to identify how to improve patient response.
- In patients considered to be good responders with higher drug trough levels, dose de-escalation may be possible without affecting clinical outcomes.
- In patients with high ADAb levels, a switch in-class may be necessary.
- In patients with low ADAb levels, the addition of an immunosuppressive drug may improve clinical outcomes.

Example of a therapeutic decision algorithm in patient with loss of response:

	Negative for ADAb	Positive for ADAb
Therapeutic level of drug	Switch out of therapeutic class	Retest
Subtherapeutic level of drug	Treatment optimisation	Switch in-class (within therapeutic class)

A complete solution for your monitoring testing needs

LISA TRACKER

Enzyme-linked immunosorbent assays (ELISA)

- Quantitative results for both drug level and anti-drug antibodies
- Validated with both original drugs and biosimilars
- Calibrated against the 1st WHO International Standard (Infliximab and Adalimumab)
- Dynamic range adapted to clinical use
- Published data
- Standardised protocols for drug levels and anti-drug antibodies
- Multiple assay formats available to suit different testing volumes

i-Tracker

Chemiluminescence immunoassays (ChLIA)

- Quantitative results for both drug level and anti-drug antibodies
- Validated with both original drugs and biosimilars
- Calibrated against the 1st WHO International Standard (Infliximab and Adalimumab)
- Dynamic range adapted to clinical use
- Highly correlated with corresponding LISA TRACKER assays
- Testing protocol managed by the system
- Ready-to-use reagents with sample dilutions managed by the system
- Time to first result: 35 minutes
- Throughput: 60 tests per hour

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Ordering information

i-Tracker

Product name	Product type	Format
CTx-002	i-Tracker Drug	100 tests
CTx-003	i-Tracker Anti-Drug	100 tests
CTz-002	i-Tracker Drug	50 tests
CTz-003	i-Tracker Anti-Drug	50 tests

x = Adalimumab / Infliximab z = Ustekinumab / Vedolizumab / Golimumab / Rituximab / Certolizumab Pegol

LISA TRACKER

Product name	Product type	Format
LTx 005	LISA TRACKER Duo Drug + Anti-Drug	2 × 48 tests
LTx 002-48	LISA TRACKER Drug	48 tests
LTx 003-48	LISA TRACKER Anti-Drug Antibodies	48 tests
LTT 004-96	LISA TRACKER TNF	96 tests

x = Adalimumab / Infliximab / Etanercept / Certolizumab Pegol / Golimumab / Rituximab / Secukinumab / Tocilizumab / Bevacizumab / TRastuzumab / Ustekinumab / Vedolizumab

IMMUNO-TROL Internal Quality Control

A range of ready-to-use, CE marked internal quality control sera for the determination of the pharmacological dosage in bio-therapies. Immuno-Trol availability corresponds to that of the associated product line.

Product name	Product type	Format
For i-Tracker assays		
CTx 002-PC	Immuno-Trol Drug: Positive control (two levels)	2 × 500 µl
CTx 003-PC	Immuno-Trol Anti-Drug Antibodies: Positive control (two levels)	2 × 1.5 ml
For Lisa Tracker assays		
LTx 002-PC	Immuno-Trol Drug: Positive control (two levels)	2 × 250 µl
LTx 003-PC	Immuno-Trol Anti-Drug Antibodies: Positive control (two levels)	2 × 1 ml

x = Adalimumab / Infliximab / Etanercept / Certolizumab Pegol / Golimumab / Rituximab / Secukinumab / Tocilizumab / Bevacizumab / TRastuzumab / Ustekinumab / Vedolizumab

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