

## **KURZPROTOKOLL** **IBIS**

<b>Öffentlicher Titel</b>	Inzidenz und wirtschaftliche Belastung von Clostridium-Difficile-Infektionen (CDI) im deutschen Gesundheitswesen
<b>Wissenschaftl. Titel</b>	Incidence and Economic Burden of Community and Hospital- Acquired Clostridium Difficile Infections (CDI) in the German Health Care System (IBIS)
<b>Kurztitel</b>	IBIS
<b>Studienart</b>	multizentrisch, prospektiv, offen/unverblindet, einarmig, Register, nicht-interventionelle Studie, Investigator Initiated Trial (IIT)
<b>Studienphase</b>	nicht zutreffend
<b>Erkrankung</b>	Infektionen: Bakterielle Infektionen
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Index episode of CDI based on:</li><li>- the presence of diarrhea (defined as <math>\geq 3</math> unformed bowel movements/24h) plus</li><li>- an enzyme immunoassay (EIA) detecting Glutamate dehydrogenase (GDH) or polymerase chain reaction (PCR) for toxin B test plus</li><li>- a positive EIA for toxin A and B</li><li>- Ongoing or new hospitalization at inclusion into the study</li><li>- Written informed consent (IC) has been obtained from the study subject or a legal representative</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Patient with any social or logistical condition which in the opinion of the investigator may interfere with the conduct of the study, such as incapacity to well understand, not willing to collaborate, or cannot easily be contacted after discharge</li><li>- CDI episode within the previous 84 days</li></ul>
<b>Alter</b>	18 Jahre und älter
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<b>Sponsor</b>	Universitätsklinikum Köln
<b>Förderer</b>	Universitätsklinikum Köln
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT03141775 (primäres Register)