

INVESTIGATOR INITIATED STUDY (IIS) APPLICATION

CONTACT DETAILS	
Date of proposal:	
Laboratory/Institute:	
City:	
Country:	
Principal Investigator:	Name: Email address: Phone number:
Curriculum vitae enclosed?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Current Idylla™ user?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Primary Idylla™ user contact details	Name: Email address: Phone number:
Do you use Idylla™ Explore?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the Idylla™ System connected?	<input type="checkbox"/> Yes <input type="checkbox"/> No

STUDY DETAILS	
Project/Study Proposal/ Scientific Abstract	<input type="checkbox"/> See attachment

	<input type="checkbox"/> Prospective <input type="checkbox"/> Retrospective		
	<input type="checkbox"/> Observational <input type="checkbox"/> Other		
	<input type="checkbox"/> Single center <input type="checkbox"/> Multi center (... sites)		
Aim of the project	Primary objective: Secondary objective:		
Do you plan to publish?	<input type="checkbox"/> Yes <input type="checkbox"/> No Estimated time of submission:		
Product ¹ / labeling ¹	<input type="checkbox"/> RUO <input type="checkbox"/> IVD	<input type="checkbox"/> APIS Breast Cancer Subtyping Kit ^{2,4} <input type="checkbox"/> APIS ESR1 Mutations Kit ^{2,4} <input type="checkbox"/> BRAF <input type="checkbox"/> CP-GEP ^{2,3} <input type="checkbox"/> ctEGFR <input type="checkbox"/> ctESR1 <input type="checkbox"/> ctKRAS <input type="checkbox"/> ctNRAS-BRAF-EGFR S492R <input type="checkbox"/> EGFR <input type="checkbox"/> GeneFusion <input type="checkbox"/> HepatoPredict ^{2,4} <input type="checkbox"/> IDH1-2 <input type="checkbox"/> KRAS <input type="checkbox"/> MSI <input type="checkbox"/> MSI 510(k) <input type="checkbox"/> NRAS-BRAF	<input type="checkbox"/> NRAS-BRAF-EGFR S492R <input type="checkbox"/> PIK3CA-AKT1 <input type="checkbox"/> POLE-POLD1 <input type="checkbox"/> ThyroidPrint ^{®2}

¹In markets where available.

²Biocartis NV is the distributor.

³Idylla™ CP-GEP (Clinicopathological Gene Expression Profiling) Assay.

⁴Not designed to be run on the Idylla™ System.

<p>Sample type</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Core needle - tissue (FFPE) <input type="checkbox"/> Resected - tissue (FFPE) <input type="checkbox"/> Cell block - cytological <input type="checkbox"/> Smear - cytological <input type="checkbox"/> Monolayer - cytological <input type="checkbox"/> Fresh (non-fixated) <input type="checkbox"/> Plasma <input type="checkbox"/> Blood <input type="checkbox"/> Extracted DNA from tissue <input type="checkbox"/> Extracted DNA from cytological <input type="checkbox"/> Touch Prep <input type="checkbox"/> Urine <input type="checkbox"/> Saliva <input type="checkbox"/> Nasopharyngeal swabs <input type="checkbox"/> Oropharyngeal swabs <input type="checkbox"/> Other, specify:
<p>Disease area:</p> <p>Total sample size (number):</p> <p>Target patient population:</p> <p>Open remark:</p>	
<p>If applicable, Reference technology</p> <p>Examples:</p> <ul style="list-style-type: none"> - NGS; the Ion AmpliSeq Cancer Hot Spot panel v2 (Illumina) - NGS; the Oncomine Solid Tumor DNA Kit (ThermoFisher) - RT-PCR; the cobas® EGFR Mutation Test v2 (Roche) - 	

<p>If applicable, Monitoring test scheme (eg ctDNA)</p> <p>Example of three time points:</p> <ul style="list-style-type: none"> - Plasma and tissue testing before surgery (baseline) - Plasma testing after surgery 3 months - Plasma testing after surgery 12 months 	
<p>If applicable, Clinical Trial number</p>	
<p>If applicable, EC/IRB approvals Informed Consent approvals</p>	<p>EC/IRB approval:</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> ongoing <input type="checkbox"/> not applicable</p>
	<p>Informed consent* approval:</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> ongoing <input type="checkbox"/> not applicable</p> <p>*capturing data and material</p>

<p style="text-align: center;">REQUEST FOR MATERIAL NEEDED FOR THE STUDY</p>	
<p>Requested number of Idylla™ cartridges</p>	
<p>Requested number of Idylla™ systems</p>	<p>Idylla™ Console: Idylla™ Instrument:</p>
<p>Timing (start/end)</p>	<p>Estimation start date: Estimation end date:</p>
<p>Other</p> <p>Examples:</p> <ul style="list-style-type: none"> - Publication cost - Support for medical writer - Cost of discordant analysis 	

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