**A1** Project Code | IPA-135 UROFollow
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**A2** Project Title | The use of biomarkers in the surveillance of bladder cancer of low and intermediate risk
**A3** External Cooperation Partners | Clinic and Polyclinic of Urology, University of Rostock  
Clinic of Urology, Eberhard-Karls-University, Tübingen  
Clinic of Urology, Waldkrankenhaus, University of Erlangen  
Department of Biophysics, Ruhr University Bochum  
Department of Urology, Helios Clinic Wuppertal, University of Witten  
Department of Urology, Marienhospital, Ruhr University Bochum  
Department of Urology, Schön Clinic Nürnberg/Fürth (Urologie24)
**A4** Project Manager(s) | Prof. Dr. Thomas Behrens  
Dr. Heiko U. Käfferlein

**B1 – Aims**
- Validation of FDA-approved biomarkers to detect recurrent bladder cancer of low and intermediate risk in a clinical trial
- Verify whether these biomarkers are comparable to regular follow-up measures (i.e. cystoscopy and cytology) of bladder cancer of low and intermediate risk to improve quality of life of patients
- Make use of the trial platform to identify, verify and validate new biomarkers for the (early) diagnosis of bladder cancer

**B2 – Trial Design**

<table>
<thead>
<tr>
<th>Arm 1 (n~250)</th>
<th>TUR-B (&quot;low-risk&quot;-Carcinomas)</th>
<th>Arm 2 (n~250)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystoscopy</td>
<td>UroVysion</td>
<td></td>
</tr>
<tr>
<td>Cytology</td>
<td>NMP22</td>
<td></td>
</tr>
<tr>
<td>Cystoscopy (Cys) after 3 months</td>
<td>Positive: Re-TURB and continue until the end of the trial</td>
<td></td>
</tr>
<tr>
<td>Follow-Up Care (Cystoscopy) (after 6, 12, 18, 24, and 30 months)</td>
<td>Biomarker and Ultrasound (after 6, 12, 18, 24, and 30 months)</td>
<td></td>
</tr>
<tr>
<td>Cys negative</td>
<td>Cys positive</td>
<td></td>
</tr>
<tr>
<td>Cys positive</td>
<td>Cys positive</td>
<td></td>
</tr>
</tbody>
</table>

36 months: End of the Study (Cys and Biomarkers)  
End of Follow Up

Additional Biomarkers which are tested in both arms (but are not used for decision-making in arm 2):
- Automated UroVysion
- UBC-Rapid
- Xpert Cepheid Bladder Cancer Monitor

**B3 – Selected Publications**