

# Protocol

Sponsor	Recruitment	Quality	Data collection
<ul style="list-style-type: none"><li>• Indemnity</li></ul>	<ul style="list-style-type: none"><li>• Who?<ul style="list-style-type: none"><li>• Children</li><li>• AWI</li><li>• Special groups</li></ul></li><li>• How?<ul style="list-style-type: none"><li>• Time to consider?</li><li>• Patient information sheet</li><li>• Consent form</li><li>• Payments?</li><li>• Adverts?</li></ul></li></ul>	<ul style="list-style-type: none"><li>• Peer review</li><li>• Power calculation</li><li>• Statistics</li></ul>	<ul style="list-style-type: none"><li>• Tissues?</li><li>• CHI number?</li><li>• ISD</li><li>• Data management</li></ul> <b>Pharmacovigilance</b> <ul style="list-style-type: none"><li>• Safety reporting</li><li>• AE recording</li></ul>