

	A Programme of Development for Older Patients with Acute Myeloid Leukaemia and High-Risk Myelodysplasia Syndrome
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PATIENT RANDOMISATION NOTEPAD 2A

(AC220 v Not) for patients with a confirmed FLT3 mutation at diagnosis
For patients who are in CR, MRD negative and received DA (+/- mylotarg) in course 1

Trials Office tel: 02922 510 530 Trials Office fax: 02920 687 501

AML 18 Trial Number:

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¹Patient's Initials: ²DoB: DD / MMM / YYYY ³Sex: Male / Female

⁴Hospital: ⁵NHS/CHI No.:

⁶Responsible Consultant: ⁷Consent Form 4 –version number signed:

⁸Person entering patient:

ELIGIBILITY CHECKLIST

Inclusion Criteria:

	YES	NO
^{9.1} Has the patient's disease status been confirmed as CR, MRD negative?	☐	☒
^{9.2} Has the patient completed 1 course of treatment?	☐	☒
^{9.3} Has the patient provided written informed consent for this randomisation?	☐	☒

Note: if the patient does not have a FLT3 mutation confirmed by the trials office they are not eligible for this randomisation and should continue with DA only in course 2.

Does the patient suffer from any of the following cardiac conditions? If YES, they are excluded from the AC220 randomisation

Known serious cardiac illness or medical conditions, including but not limited to:

	YES	NO
^{10.1} Clinically unstable cardiac disease, including unstable atrial fibrillation, symptomatic bradycardia, unstable congestive heart failure, active myocardial ischemia, or indwelling temporary pacemaker	☒	☐
^{10.2} Ventricular tachycardia or a supraventricular tachycardia that requires treatment with a Class Ia antiarrhythmic drug (e.g., quinidine, procainamide, disopyramide) or Class III antiarrhythmic drug (e.g., sotalol, amiodarone, dofetilide). Use of other antiarrhythmic drugs is permitted	☒	☐
^{10.3} Use of medications that have been linked to the occurrence of torsades de pointes (see Protocol for the list of such medications)	☒	☐
^{10.4} Second- or third-degree atrioventricular (AV) block unless treated with a permanent pacemaker	☒	☐
^{10.5} Complete left bundle branch block (LBBB)	☒	☐
^{10.6} History of long QT Syndrome or a family member with this condition	☒	☐
^{10.7} QTc >450 ms (average of triplicate ECG recordings); a consistent method of QTc calculation must be used for each patient's QTc measurements. QTcF (Fridericia's formula) is preferred	☒	☐
^{10.8} Serum potassium, magnesium, and calcium levels outside the laboratory's reference range	☒	☐

Information to be obtained from the trials office

☐

DA (50mg)

Small Molecule
(if eligible)☐

AC220 Short

☐

None

☐

AC220 Long

Date of entry:

Signature: _____

Date: