REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS THIS REPORT IS BEING SENT TO: 1) NHS England
1	CORONER I am Alison Mutch, Senior Coroner, for the coroner area of South Manchester
2	CORONER'S LEGAL POWERS I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013
3	INVESTIGATION and INQUEST On 1st November 2023 I commenced an investigation into the death of Linda MCLAUGHLIN. The investigation concluded on the 16th May 2024 and the conclusion was one of NARRATIVE: Died from bronchopneumonia contributed to by the complications of previous drug therapy. The medical cause of death was **1a) Bronchopneumonia II) Drug induced Interstitial Lung disease, Chronic Myeloid Leukaemia, Steroid therapy.**
4	CIRCUMSTANCES OF THE DEATH In 2014 Linda McLaughlin was diagnosed with Chronic Myeloid Leukaemia (CML) and treated with a tyrosine kinase inhibitor drug (nilotinib). She responded well to the treatment and by October 2021 was in molecular remission. She remained on a low dose of nilotinib. In April 2023 she was becoming increasingly breathless and went to Royal Oldham Hospital where a scan in May 2023 found she had developed interstitial lung disease probably as a consequence of nilotinib treatment. She was treated with steroids for interstitial lung disease and the nilotinib was stopped. On 23rd October 2023 she was admitted to Tameside General Hospital where she was treated for bronchopneumonia and was very unwell. She deteriorated and died at Tameside General Hospital on 27th October 2023
5	<u>CORONER'S CONCERNS</u>

	During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. The MATTERS OF CONCERN are as follows. – 1. The inquest heard evidence that the complication that Mrs McLaughlin developed is rare but recognised internationally. However it is not widely known about and as a consequence of lack of awareness even amongst oncologists/haematologists it may not be recognised that a patient has symptoms of interstitial lung disease and as a consequence referral and treatment that could slow the disease progression may be delayed. 2. The inquest was told that the consenting process for starting a patient on a drug such as nilotinib would not ordinarily include mentioning rare complications such as interstitial lung disease. The family gave evidence that in this case this is something that would have been carefully weighed in the decision to proceed with the treatment. 3. In this case the inquest was told that a decision was taken to continue with nilotinib despite being in remission. The inquest was told that there is growing evidence that some people do not need to stay on these drugs for life if in remission but there is no clear guidance for the approach to take. As a consequence patients may remain on the drug longer than necessary.
6	ACTION SHOULD BE TAKEN In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action.
7	YOUR RESPONSE You are under a duty to respond to this report within 56 days of the date of this report, namely by 8th August 2024. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	COPIES and PUBLICATION

	I have sent a copy of my report to the Chief Coroner and to the following Interested Persons namely [redacted] on behalf of the family, who may find it useful or of interest. I am also under a duty to send the Chief Coroner a copy of your response. The Chief Coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the Chief Coroner.
9	**Alison Mutch** **HM Senior Coroner**  **13.06.2024**