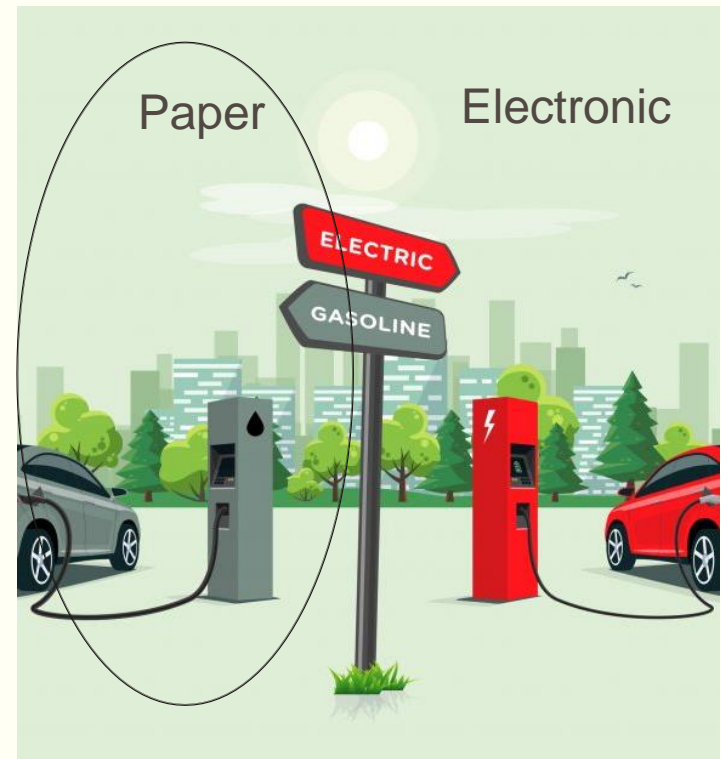


# Study Director Perspective on GLP Paper Field Notebooks

## “The Reality”

Michelle M. Baillargeon, Ph.D.  
The Carringers, Inc.

2024 NAICC Meeting – San Antonio, TX



# The Journey

<https://www.cartoondealer.com/image/86950059/mobile-gps-navigation-map.html>

## Regulatory Guidelines



<https://www.freevector.com/road-signs-vectors>

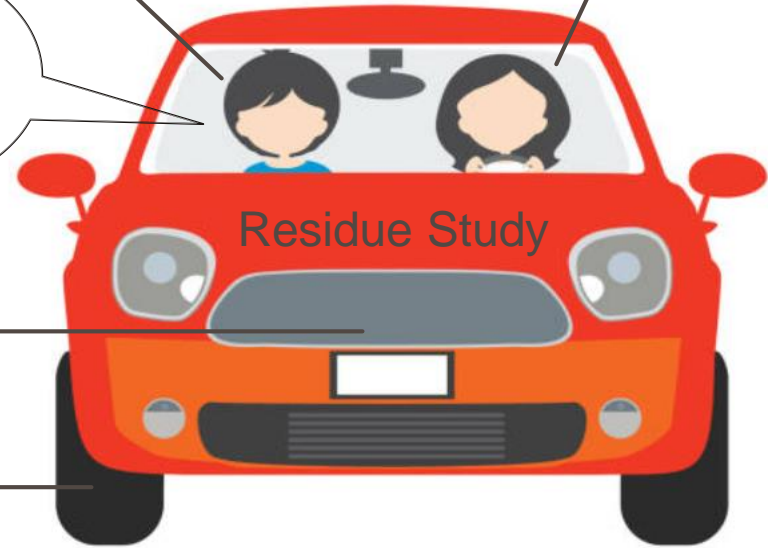
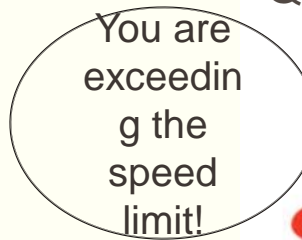
Protocol



Study Plan

QA Officer

Study Director



<https://www.istockphoto.com/illustrations/cartoon-of-usable>

Processing Facility and Analytical Laboratory

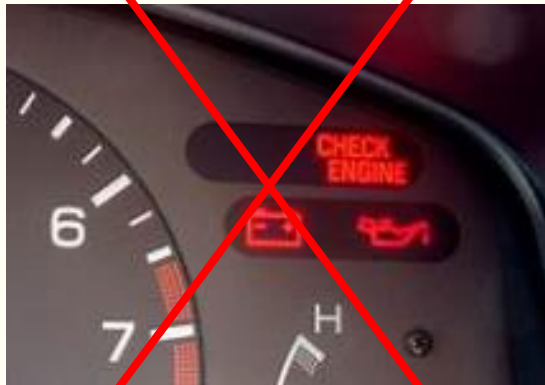
Field Trials

**If the wheels come off, the vehicle is NOT going anywhere!**

# Preventative Maintenance

## Vehicle:

- Check Fluids
- Tire Pressure
- Scheduled Maintenance
- Fill-Up with Gasoline



<https://reliable-auto.com/top-reasons-your-check-engine-light-might-be-on/>

## Paper Notebook:

- **Read Protocol/Study Plan**
- Review the Notebook  
(Feedback on Forms to SD is useful)
- Review Sample Labels and Prepare Sample Bags at Trial Initiation
- Document Promptly and Add Pages if Needed
- **Send Application/Sampling Pages to SD (72 hours)**

**AVOID the “PFI Oversight”  
Deviations or Trial Failure**

# Occasionally a Few Wrecks

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- Illegible handwriting!
- Messy
- Incomplete documentation
- Errors not corrected per GLPs
- Incorrect significant figures
- Trial number not on all pages
- Missing: units of measure, postal code, GPS coordinates on plot map, location of weather station, initials, and/or date
- Wrong information documented
- Calculations: incorrect or inconsistent across trial sites



<https://www.shopshirestar.com/news/local-hubs/shrewsbury/2017/07/28/Ferrari-wrecked-after-smashing-into-wall-shrewsbury--with-pictures/>

# Repairs

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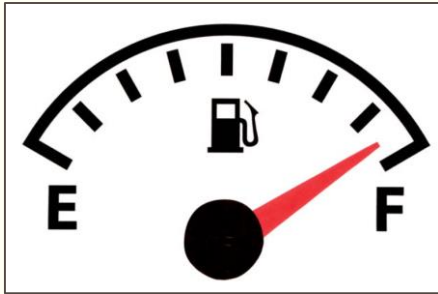


- Get training/ask for help
- Slow down/take time
- Review entries for accuracy and completeness
- Make corrections per GLPs!



# Don't Run Out of Gas

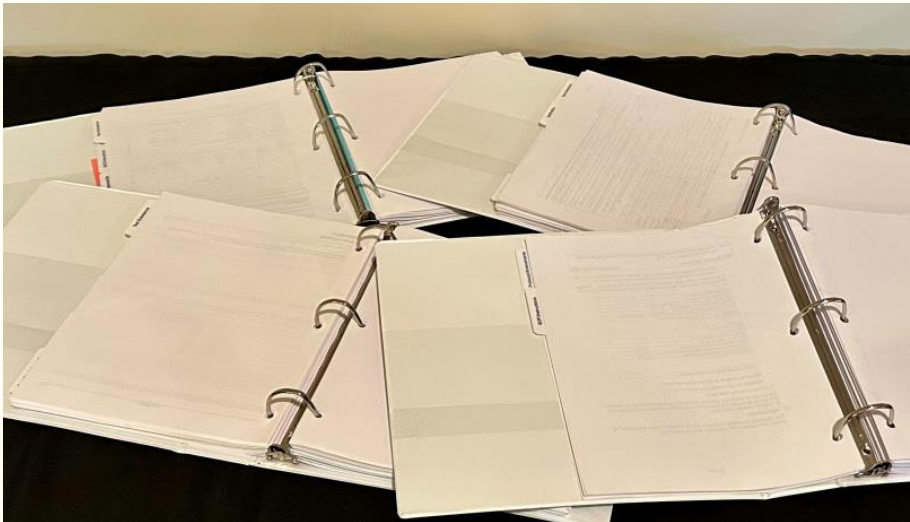
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<https://www.clipartmag.com/tag/gauge>

Return notebook to Test Facility

- Promptly
- Delivered to correct address!
- Certified/signature not required



# Thank You!

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